

2001 RISPERDAL®

BUSINESS PLAN SUMMARY



TABLE OF CONTENTS

Executive Summary (Brand Overview)

Base Business Plan

- I. Executive Summary
- II. Situation Diagnostic Analysis
- III. Product Performance Summary
- IV. SWOT Analysis/Key Issues
- V. 2001 Strategic Objectives
- VI. Key Business Strategies
- VII. Key Programs and Tactics
- VIII. Success Predictors

Geriatric Business Plan

- I. Executive Summary
- II. Situation Diagnostic Analysis
- III. Product Performance Summary
- IV. SWOT Analysis/Key Issues
- V. 2001 Strategic Objectives
- VI. Key Business Strategies
- VII. Key Programs and Tactics
- VIII. Success Predictors

Affective Disorders Business Plan

- I. Executive Summary
- II. Situation Diagnostic Analysis
- III. Product Performance Summary
- IV. SWOT Analysis/Key Issues
- V. 2001 Strategic Objectives
- VI. Key Business Strategies
- VII. Key Programs and Tactics
- VIII. Success Predictors

Appendices:

- Summary
- Competitive Overview
- Competitive Spending
- Market Research Plan
- Tactical Plan

Executive Summary:

Brand Overview: The antipsychotic market is valued at approximately \$4.0 billion (in 2000); an increase of 23% vs. 1999. Growth is due to a combination of the continued conversion of conventional antipsychotics, market expansion due to new label changes, increased promotional activities, and line extensions. In 2000, Zyprexa achieved two label changes ("acute mania associated with bipolar disorder" and 'long-term maintenance treatment') and a line extension (Zydis). In 2001 the market will further increase due to: (1) the launch of a short-acting Zyprexa formulation; (2) the launch of Pfizer's Zeldox (March); and (3) a significant spend by Novartis and BMS/Otsuka via medical education activities to support the launch of its anti-psychotic.

RISPERDAL has been the #1 prescribed antipsychotic in the US for over 4 years. The December 2000 TRx share of 31.3% represents an all time high for RISPERDAL. This compares Zyprexa at 25.2%, and Seroquel at 10.5%. In 2001 it is critical to further differentiate RISPERDAL from the competition through a competitive share of voice, using appropriate clinical data, launching new indications and maximizing additional formulations.

Schizophrenia is the foundation of the antipsychotic market and represents the greatest dollar potential. The base business is primarily comprised of the schizophrenia market and our current share in this market is about 20.8% (MAT Nov 2000), compared to 26.9% for Zyprexa. In 2001 growing our base business is a critical area of focus. In 2001 we will also appropriately leverage the data and the business opportunity within the child/adolescent market via medical education. The base business is forecasted to contribute \$535 MM to the year-end brand target of \$1,207MM; a 10% increase vs. 2000.

The 2001 objective is to maintain our schizophrenia to a 20.8%. Key strategies are:

- (1) to differentiate RISPERDAL from the competition by - driving competitive positioning versus Zeldox; enhancing our efficacy & diabetes profile; neutralize EPS and TD perceptions; aggressively expedite CDP: launch new indications and formulations; and strategically target key publications for dissemination, and
- (2) to protect and expand our reach/partnerships within our key customer base and within the acute setting, among residents, child/adolescents, psychiatric nurses and the pharmacy.

The *geriatric* market represents RISPERDAL's second largest revenue opportunity. About 4MM people struggle with dementia and demographic trends will continue to drive market growth. RISPERDAL remains the #1 prescribed antipsychotic in LTC in terms of both market share and dollars. RISPERDAL's NRx LTC share is at 34.1% compared to 23.6% for Zyprexa (IMS Health, Dec. 2000). Looking specifically at Omnicare (60% of the LTC market and not included in IMS audits), RISPERDAL share is approximately 48% versus 18% for Zyprexa. An increasing resource focus by Lilly and Astra-Zeneca is making this a much more competitive segment. Our goals in 2001 are to grow share and more accurately measure our leadership position. We will achieve sales of \$360 million; an 18% increase vs. 2000. We are targeting an APS 3-9 market share of 36% and LTCPP DACON market share of 61%.

The brand will achieve these business goals by implementing tactics against 4 key strategies:

- (1) strengthening our efficacy/safety positioning
- (2) expand into additional market segments, i.e., elderly psychosis
- (3) expand reach and educate a diverse audience, and
- (4) effectively position and maximize RISPERDAL & REMINYL

To maximize and maintain RISPERDAL's leadership position it is essential the registration trials for the indication 'psychosis in dementia' must remain on their timelines.

RISPERDAL use in *affective disorders* represents about one-third of total prescriptions. Bipolar disorder is one of the most significant opportunities within this overall market. Among antipsychotics, RISPERDAL's share of bipolar patients is 27.2% versus 38.2% for Zyprexa and 13.6% for Seroquel

[NDTI, MAT 11/00]. Following the approval of Zyprexa for acute mania in March, the overall Zyprexa share has increased substantially.

In the coming years, Johnson and Johnson will be in the unique position of having both RISPERDAL **RED** **REDACTED** approved for the treatment of bipolar disorder. The current treatment paradigm is to use both an anticonvulsant and an antipsychotic. We will put in place appropriate plans to leverage and maximize both products as the treatment combination of choice. Our goal is to further differentiate RISPERDAL from other agents in bipolar disorder, to establish its role in the treatment paradigm, and to execute our clinical development plan to gain regulatory approval. In addition to bipolar depression, RISPERDAL's potential in refractory depression will be assessed and if indicated a clinical program will be pursued.

The key strategies for our affective business are:

- (1) to differentiate RISPERDAL as the preferred antipsychotic in bipolar disorder **REDACTED**
- (2) position RISPERDAL **REDACTED** as the optimum combination for bipolar disorder, and
- (3) determine the clinical/financial viability of commercializing RISPERDAL for add-on therapy in depressive disorders.

The RISPERDAL franchise will have two new formulation sNDAs planned in 2001. The first submission is Quicksolv (0.5, 1 and 2 mg tablets) a rapidly dissolving formulation. The two most important opportunities for Quicksolv are in the acute setting and for the elderly. Quicksolv will be an important introduction as it allows us to be competitive with Lilly's rapidly dissolving Zydys formulation, launched in 2000.

Our second submission is Microspheres, a long acting injectable formulation of RISPERDAL that can be used every two weeks. RISPERDAL will have a major advantage as it will be the first atypical with this key formulation. The largest opportunity for Microspheres is in the schizophrenia market with a portion of the business also in treatment of bipolar disorder.

Overall key issues for RISPERDAL in 2001 are:

- (1) to effectively respond to the increasing competitive intensity
- (2) to appropriately maximize the untapped market opportunities, i.e., pediatric and elderly psychosis markets
- (3) respond to the educational needs on appropriate use and benefits of atypicals
- (4) improve the currently unfavorable label for RISPERDAL, and
- (5) maximize RISPERDAL's & REMINYL's co-positioning

The 2001 business goal is to attain total RISPERDAL sales of \$1.207 billion with a TRx exit share of 29.6%. RISPERDAL is the antipsychotic of choice and from this position of strength we will grow Janssen's business opportunities and leadership in the CNS market. Our focus is to use appropriate promotional platforms to enhance our recognized leadership position as the most effective antipsychotic for first-line treatment in schizophrenia/psychosis. In addition, using appropriate medical education prescribers will understand how to effectively use RISPERDAL in other indications like bipolar disorders, dementia and conduct disorder. The brand team will also be building a very solid foundation to launch future RISPERDAL line extensions (microspheres and QS). We will also work closely with our business partners on the REMINYL **REDACTED** teams to appropriately and effectively leverage each molecule across our diverse customer base.

2001 Base

Business Plan

I. EXECUTIVE SUMMARY:

The antipsychotic market is valued at approximately \$4.0 billion, representing an increase of 26% over last year. Schizophrenia is the foundation of overall antipsychotic use, and represents the largest dollar potential (\$1.3 billion in RISPERDAL dollars). Overall growth in the schizophrenia segment of the market is flat. Although the RISPERDAL Base business is rooted in the Schizophrenia marketplace, another fast-growing portion of this market is in children and adolescents. The child/adolescent antipsychotic segment (19 years and under) is growing at a rate of 17%, and is currently valued at approximately \$340 million. Use of RISPERDAL in this segment has grown 50% in the past two years, and prescriptions in this category account for 20% of overall RISPERDAL use. RISPERDAL has remained the #1 prescribed antipsychotic in the United States for over 4 years. The current NRx share of 32.0% represents an all time high for RISPERDAL. RISPERDAL share in schizophrenia is at 19.6% (MAT Sept 00), while share in child/adolescents for RISPERDAL is at >54% share.

2001 will be a challenging year for the RISPERDAL base business. A new competitor (Zeldox), is likely to be approved in the first quarter. Zyprexa has achieved one label change (maintenance) in 2000, and one line extension (Zydis), with an IM formulation approval expected mid-2001. Seroquel growth has exploded in the past year (+3.1% YTD Oct 00). The key issues for RISPERDAL in 2001 are:

1. Increasing competitive intensity
2. Lack of competitive product development program
3. Insufficient generation & dissemination: Phase IV data
4. Reimbursement environment becoming more scrutinized
5. Sub-optimal salesforce deployment/alignment

Some issues are emerging and market place assumptions developing that could put RISPERDAL base business in a solid position for significant growth:

- The FDA is looking at diabetes data on all atypical antipsychotics. Current data suggests that Zyprexa and Clozaril have a much greater diabetes liability than RISPERDAL.
- Zeldox could be introduced to the market with restrictive cardiac labeling.
- RISPERDAL use in the acute setting is gaining in acceptance.
- RISPERDAL use in the child/adolescent population is exploding.

In 2001, base business will remain a critical area of focus for the RISPERDAL brand. Base business is forecasted to contribute \$535 MM (10% increase over last year) to the overall year-end brand goal of \$1.207 MM. Qualitative base business goals are to grow share in schizophrenia and overall base business, with an additional focus on the acute setting. In addition, we will continue to build upon pre-marketing activities for RISPERDAL use in the child/adolescent market. The quantitative goal will be to grow share in schizophrenia with an exit share of 20.0%.

The RISPERDAL positioning message is as follows: RISPERDAL offers clinicians and their patients the best combination of efficacy and safety.

- Superior efficacy as soon as week 1, maintained through year 1
- Excellent safety profile with low incidence of diabetes, safe cardiac profile, low weight gain, rare TD and low EPS
- Easy, once a day dosing

In order to be successful in 2001, we must:

1. Differentiate RISPERDAL from the Competition
2. Protect and Expand Reach/Partnership with Key Customer Base
3. Proactively Maximize Cost and Reimbursement Opportunities
4. Maximize Salesforce Impact

II. SITUATIONAL ANALYSIS:

Market Overview

The antipsychotic (APS) market is valued at approximately \$4.0 billion [2000 estimate, IMS Health] (\$3.6 billion estimated in RIS NTS dollars), representing a dollar increase of 26.0% from last year. It is projected that this increase in dollar volume will continue for 4 reasons:

1. The market is continuing to rapidly convert from generic conventional antipsychotic use to more expensive atypical antipsychotics. Conventionals have lost 8.2 NRx share points to atypicals in the last 12 months.
2. Atypical competitor Zyprexa is expanding the APS market due to new indications beyond schizophrenia (acute mania) and line extensions (Zydis and IM).
3. Atypical competitor Seroquel is expanding the APS market due to extensive off-label use (sleep aid, mild disease states)
4. The entry of new atypical competitor Zeldox in the first quarter will increase the rate of conventional switches, and based on their positioning, is expected to expand the market beyond schizophrenia.

RISPERDAL has remained the #1 prescribed antipsychotic in the United States for over 4 years. The current NRx share of 32.0% (October 00) represents an all time high.

In 2001, base business will remain a critical area of focus for the RISPERDAL brand; mainly comprised by the schizophrenia market, and to a lesser extent, the child/adolescent market. Base business is forecasted to contribute \$535 MM (10% increase over last year) to the overall year-end brand goal of \$1.207 MM. Qualitative base business goals are to grow share in schizophrenia and overall base business, with an additional focus on child/adolescents and the acute setting.

Schizophrenia is the foundation for overall antipsychotic use and represents the largest dollar potential (\$1.3 billion in RISPERDAL dollars). Overall growth in the schizophrenia market is flat. RISPERDAL currently has 19.6% share (MAT Sept 00) of the schizophrenia market, compared to 26.1% for Zyprexa, and 10.0% for Seroquel. RISPERDAL was at 17.0% share in December of 1999, growing its share 2.6% in the past nine months. In 2001, the quantitative goal will be to grow share in schizophrenia with an exit share of 20.0%.

The child/adolescent antipsychotic market (19 years and under) segment is growing at a rate of 17%, and is currently valued at approximately \$340 million. Use of RISPERDAL in this segment has grown 50% in the past two years. RISPERDAL prescriptions in this category account for 20% of overall RISPERDAL use. RISPERDAL currently has over a 54% share, compared to 21% for Zyprexa, and 9% for Seroquel (NDTI, MAT Sept 00). The success of RISPERDAL in children/adolescents is largely due to its use in the following diagnoses: bipolar disorder (21%), autism (18%), ADHD (15%), schizophrenia/other psychoses (20%). The target symptoms for which RISPERDAL is typically prescribed is to control aggressive/impulsive behavior. There has been very little data published to date regarding the use of RISPERDAL in this patient population. However, a few case reports and letters to the editor have been highly influential, as prescribers are searching for safer antipsychotics than Haldol and Mellaril. New well-controlled studies have recently been completed for RISPERDAL, and it is expected that these studies will continue to drive use in this patient population.

Customer Segment Overview

RISPERDAL is largely driven by retail sales (63%), while institutional business contributes 12% and the long-term care segment an additional 20%. Managed care and Medicaid are the largest payor segments, representing about 46% and 42% of total prescriptions, respectively (IMS Health, Plantrak, YTD 6/00). There are few formulary barriers to RISPERDAL prescriptions, and in the states of Texas and Florida it is the preferred antipsychotic.

There are approximately 39,967 psychiatrists in the United States. Of the total psychiatrists, we target approximately 18,300 psychiatrists who are the top prescribers of the antipsychotic class. These physicians are found mainly in the community mental health centers, but are also in the institutional

setting (including ER), in private practice, or in a managed care system. Top antipsychotic prescribers typically treat the seriously mentally ill, with the vast majority of their patients diagnosed with schizophrenia or schizoaffective disorder, and to a lesser degree, bipolar disorder. These same psychiatrists may also see children/adolescents with behavioral disorders, although the treating psychiatrist may or may not be specially trained in child psychiatry.

Included in the 39,967 psychiatrists in the United States, there are approximately 5,685 board-certified child psychiatrists. Antipsychotic use is growing with these physicians, as they look to control behavioral issues that have not responded to the typical first or second line agents. The use of RISPERDAL in the child/adolescent market has grown at a rate of 50% in the past two years, outpacing the growth of the overall antipsychotic pediatric market, which is growing at a rate of 17%.

Residents in psychiatry represent yet another key customer base. There are 220 accredited psychiatric residency programs in the United States, with each program training between 10-40 residents. Gaining contact and building relationships with this group is crucial to the ongoing success with RISPERDAL and for laying groundwork for other Janssen/J&J CNS compounds.

Psychiatric nurse practitioners (NPs) are a very important segment of the business, particularly in the Pacific Northwest and the state of Massachusetts. Psychiatric NPs have prescribing privileges in 46 states. Janssen representatives have been calling on some of these customers, but have not been receiving pharmacy credit for nurse practitioner prescriptions to date. Plans have been laid in 2001 for better targeting of these nurses, and for sales compensation for representatives.

Institutional pharmacists remain a key customer segment for Janssen. RISPERDAL has a significant cost advantage over Zyprexa, and with the forthcoming introduction of Zeldox to the market, it is likely that institutions will tighten formularies and look at restrictions.

Competitive Overview

Zyprexa, marketed by Eli Lilly, is the number two prescribed antipsychotic in overall market share (NRx 26.4%, Oct 00), although it is number one in overall sales, due to a significantly higher cost per prescription than RISPERDAL. Zyprexa is the number one prescribed antipsychotic for schizophrenia (NDTI 26.1%, Sept 00), although its NDTI share in schizophrenia has been flat, growing only 0.4% since December of 1999. Zyprexa was introduced into the market in October of 1996, and was touted as Clozaril without the side effects. Although that halo effect has remained to some degree, prescribers have found that the core efficacy of Zyprexa is not that of Clozaril, but side effects such as significant weight gain and glucose elevation are emerging as being quite similar. Zyprexa is currently positioned as offering superior efficacy, with a particular focus on cognition and mood symptoms. Lilly minimizes any weight issue or elevated glucose issue, and spends a great deal of time positioning RISPERDAL as causing dangerous prolactin elevation, a high level of EPS, and higher TD than Zyprexa.

In fact, since the launch of Zyprexa, they have focused on saying that RISPERDAL straddles atypicality and typicality due to higher EPS, and therefore, higher TD potential. Physicians do "buy in" to the efficacy of Zyprexa in mood symptoms, and tend to prescribe it in schizophrenic patients with concurrent mood symptoms. Zyprexa is not used as frequently in the child/adolescent population due to its significant weight gain potential. Zyprexa launched a quick-dissolving wafer (Zydis) in September of 2000, and is expected to gain approval for an IM formulation in June of 2001. Zyprexa would be the first atypical to market an IM formulation, although Zeldox may be filing its IM formulation in the first quarter of 2001. Eli Lilly's flagship product, Prozac, will go off patent in 2001. As a result, they are placing an even greater emphasis on driving the growth of Zyprexa, and are increasing marketing dollars as well as shifting sales force capacity away from Prozac to Zyprexa.

In the spring of 2000, the FDA requested that all companies currently marketing atypical antipsychotics submit detailed data on diabetes and glucose elevation, due to an increasing number of reports in the literature tying certain atypicals with causing elevated glucose, type II diabetes and diabetic ketoacidosis. The vast majority of those published cases, letters to the editor, poster presentations and

prospective/retrospective studies have focused on Clozaril and Zyprexa. There have also been case reports for Seroquel, which is surprising given the fewer number of prescriptions that have been written for that product. RISPERDAL has also been mentioned, but at a greatly reduced rate. Although we do not know what the FDA intends to do with the data submitted, it is possible that it may have serious product labeling ramifications, especially for Clozaril and Zyprexa.

Seroquel, marketed by Astra-Zeneca is the number three atypical antipsychotic prescribed overall, with an overall market share of 11.0% (October 00), and a 10.0% share in schizophrenia (Sept NDTI). Seroquel has modest efficacy, but is positioned as the atypical with the best safety profile: no EPS, minimal weight gain, and no prolactin elevation. Astra Zeneca is targeting RISPERDAL prescriptions by positioning RISPERDAL as having significantly more EPS and TD. Seroquel is also being positioned as a sleep aid, or prescribed when just "a touch" of antipsychotic is needed. While physicians have found that Seroquel has minimal efficacy, they do not hesitate to co-prescribe it with other antipsychotics. In fact, Seroquel is co-prescribed with another antipsychotic over 40% of the time in patients with schizophrenia. It is interesting to note that in an intensive cardiac comparison trial, conducted by Pfizer, Seroquel appeared to have a higher propensity for QT prolongation than RISPERDAL or Zyprexa. In addition, more case reports of type II diabetes are emerging in the literature for Seroquel as well. Seroquel may have been "written off" as a virtual non-competitor at its launch, but it appears that its safety message is meaningful for many prescribers. Therefore, we will be moving forward with a more aggressive, targeted message versus Seroquel than we have in the past.

Zeldox, a new atypical soon to be marketed by Pfizer, has been delayed with the FDA for two years, due to cardiac safety concerns. The FDA asked Pfizer to conduct an extensive cardiac safety study comparing the atypicals, which was presented to the FDA in July of 2000. Zeldox was given an approvable letter by the FDA in September of 2000, and is currently believed to be working on final label negotiations. Zeldox is expected to launch in the first quarter of 2001, but may have restrictive cardiac labeling. Pfizer will focus their core message on: efficacy equal to other atypicals, superior effects in cognition and mood, and no weight gain. Cardiac safety aside, Zeldox offers modest efficacy (equal to Haldol), low/dose-dependent EPS, and low weight gain. It appears to have some issue with nausea. Zeldox has to be dosed BID, with food, which affects absorption. It is expected that Zyprexa will be the most affected by the entry of Zeldox, since Pfizer is taking direct aim at Zyprexa with weight gain and glucose concerns. However, Pfizer is also focusing on EPS and TD as key differentiators versus RISPERDAL. Pfizer has filed it's application for an IM formulation, and an FDA advisory panel will convene on February 15 to discuss this line extension.

The antipsychotic market has undergone radical changes in the past seven years, with more changes to come. With the exception of Clozaril, introduced in 1990, the antipsychotic market had not changed since the 1960's, when the first conventional antipsychotics were introduced. With the introduction of RISPERDAL in 1994, the antipsychotic market began to rapidly evolve. Zyprexa was launched in 1996, Seroquel in 1997, Zeldox is expected to launch in early 2001, and aripiprazole and iloperidone are expected to launch in 2002. Psychiatrists who had little prescribing choices just seven years ago, will soon have six atypical antipsychotics from which to choose. Similar to what occurred with the high versus low potency conventional antipsychotics, it appears that the market is shifting in regard to the core message "battleground." While efficacy will always be important, it is likely that prescribers will lump all atypicals into an efficacy "class effect", and differentiate between them based upon side effect profiles. Accordingly, while we will continue to stress the superior efficacy of RISPERDAL, we will take a much stronger approach to differentiating on serious side effects: low diabetes and safe cardiac profile.

III. PRODUCT PERFORMANCE SUMMARY:

2000 Qualitative Goals:

To accelerate growth in schizophrenia, with the ultimate goal of recapturing the lead.

Status as of October, 2000:

RISPERDAL has grown from 17.0% to 19.6% since December 1999, while Zyprexa has only grown 0.4% in the same time period.

2000 Quantitative Goals:

Base Business Sales: \$583 MM (category defined differently in 00' vs 01')
December schizophrenia share: 20.0%

Status as of October 2000:

We are on track for base business sales.
RISPERDAL is only 0.4% away from reaching 20.0% goal in schizophrenia

2000 Critical Success Factors

- ◆ Publish Relapse Prevention and RIS Vs OLZ Studies
- ◆ Eliminate Perceptual Gap RIS Vs OLZ: Negative Symptoms
- ◆ Lessen Perceptual Gap RIS Vs OLZ: EPS
- ◆ Elevate awareness of OLZ diabetes risk
- ◆ Execute Ziprasidone Blocking Strategy: 100% completion of training by September 2000

Accomplished YTD

Submitted
Done

Done
Done

2000 Strategies

- Differentiate RISPERDAL from the competition
- Expand reach on key customer base
- Solidify & expand opinion leader support
- Explore compliance opportunities
- Maximize cost and reimbursement opportunities

Differentiate RISPERDAL from the Competition

<u>Program</u>	<u>Committed</u>	<u>Achieved YTD</u>
Zeldox Blocking Kit		September '00
Influence Network Mktg	27	cut (frozen funds)
CNS Advisory Forums	20	18
Teletopics	4	4
DLN	4	4
Speaker Training	2	1 (1 cut-frozen funds)
RISPERDAL.com	Q1 '00	March '00
Portable Virtual Hallucinations	4 machines	8 machines
Sales Training Audiotapes	4	3
Promotional Patient Video	1	1
Progress in Schizophrenia CME	8	8

Expand Reach on Key Customer Base

<u>Program</u>	<u>Committed</u>	<u>Achieved YTD</u>
Janssen Resident of the Year	1	1
ER Education Pack	1	1
APNA Newsletter	6	6
APIRE Residents Program	1	1
RN Practical Workshop	3	cut (frozen funds)

Expand Opinion Leader Support

<u>Program</u>	<u>Committed</u>	<u>Achieved YTD</u>
Speaker Intranet	Q1 '00	Q2 '00
CNS Summit	Q1 '00	Q1 '00
Emory Young Faculty	Q2 '00	Q2 '00

Explore Compliance Opportunities

<u>Program</u>	<u>Committed</u>	<u>Achieved YTD</u>
DTP Pharmacy Intervention	Q3 '00	cut (frozen funds)
Discharge Planning Kit	Q3 '00	Q3 '00
Compeer Program	Q1 '00	Q1 '00

Maximize Cost and Reimbursement Opportunities

<u>Program</u>	<u>Committed</u>	<u>Achieved YTD</u>
DUE (MUE) Form	2	1 in progress
Public Sector Forums	10	14
Guideline Development	3	15
Reduce GPO Rebates	(targeted GPOs)	5
Performance Guarantee Program		new starts 2000+

2000 Lessons Learned for 2001

- **Perceived superior efficacy is not enough; safety must also be redefined**
TD and EPS are stumbling blocks that must be neutralized
Diabetes must be seen as CLEAR differentiator
Physicians buy into RIS lower weight gain
Aggressively pre-position Ziprasidone QTc
- **Data flow is CRUCIAL - INVEST EARLY!**
Outgunned in publication, volume, breadth and dissemination
WLF has impact
- **Ziprasidone is perceived to have an attractive profile**
Perceived "win" on efficacy and safety balance
- **We need increased competitive scientific headcount deployment**
- **Short-term opportunities in pediatrics and the acute setting exist**
- **We have gained increased RISPERDAL payer coverage by expanded investment**

IV. SWOT ANALYSIS/ KEY ISSUES:

Strengths

- #1 prescribed APS overall
- # 1 Pediatric APS
- Efficacy perceptions
- Low weight gain
- Low diabetes profile
- Data in conduct disorder
- Motivated SF/call plan execution
- Cost advantage/reimbursement wins
- Opinion leader relationships
- Nimble development/implementation of marketing tools
- Tenure of Sales Force/Mgt teams

Opportunities

- Position RIS as best-balanced APS:
 - efficacy & safety
- Leverage competitor diabetes & QTc
- Secondary analyses: 112, 79, 93, 97
- Label changes (AE's, dosing, indications)
- Expanding customer reach
 - pediatric data, residents, neurology
- Expand I & IMD reps
- Schizophrenia promotion by Eldercare SF
- Increased regional med. affairs presence
- Increased e-business reach
- E-POC launch

Weaknesses

- #2 prescribed APS in schizophrenia
- Perception on EPS/TD
- Product development plan
 - Lack of resources to drive data
 - Lack of data/risk averse
 - Slow speed to market
- Publication strategy/performance
 - Slow/missed secondary analyses
- Product labeling:
 - dosing recommendations
 - no new indications since launch

Threats

- Zeldox launch
- Zyprexa launches
 - Zydys & IM
 - relapse-prevention
 - agitation: superior to haldol
- J & J position on WLF
- Seroquel penetration
- Delays/execution in CDP
- Depot program
 - potential delays
 - head to head trial vs Zyprexa
- APS Diabetes class labeling
- Medicaid reform: price controls

KEY ISSUES:

1. Increasing competitive intensity

- Diluted Share of Voice with key customers (sales, medical, public health systems)
- Competitor focus on RISPERDAL increased risk EPS/TD profile (x 3)
- New formulations/indications/studies/publications
- E-business landscape

2. Lack of competitive product development program

- Lack of resources to drive data
- Lack of data/new labeling
- Risk averse/slow speed to market
- Limited product differentiation

3. Insufficient generation & dissemination: Phase IV data

- Inadequate plan/resources
- Non-competitive approach to WLF and promotional issues

4. Reimbursement environment becoming more scrutinized

- Budgetary pressures at state/local levels

5. CNS Sales Force

- Overall low tenure
- Limited training continuum

V. 2001 STRATEGIC OBJECTIVES:

Qualitative Goal

Grow share in schizophrenia and overall base business, with an additional focus on children/adolescents and the acute setting.

Quantitative Goal

\$535 MM

One-Year Financial Targets

Sales	\$535MM
Growth	+ 10% versus 2000
Expenses	+ 2% versus 2000
ROI	

One-Year Marketing Objectives

- Significantly increase diabetes awareness with Zyprexa; shift diabetes attribute perception into the "more important" attribute category (perceptual maps); make this a part of the basis for choosing RISPERDAL
- Raise awareness and importance of cardiac issues with Zeldox via medical education and promotional campaign
- Neutralize EPS and TD concerns; shift perception to neutral territory (perceptual maps)
- Grow and protect share in children/adolescents via medical education/publication of new data
- Minimize entry impact of competitive IM formulations by driving "oral is better"
- Minimize Zeldox entry to less than 8% market share at year-end 01', assuming second-line status
- Stop continued Seroquel growth

VI. KEY BASE BUSINESS STRATEGIES:

RISPERDAL Positioning:

RISPERDAL offers clinicians and their patients the best balance of efficacy and safety

Key Strategies

1. Differentiate RISPERDAL from the Competition
 - drive competitive stance versus Zeldox
 - enhance favorable perceptions: efficacy & diabetes; neutralize EPS and TD
 - aggressively expedite CDP: launch new indications and formulations
 - strategically target key publications for WLF distribution

2. Protect and Expand Reach/Partnerships with Key Customer Base
 - acute setting
 - residents
 - child/adolescents
 - psychiatric nurses
 - pharmacy
3. Proactively Maximize Cost and Reimbursement Opportunities
4. Maximize Salesforce Impact

VII. KEY PROGRAMS AND TACTICS:

See full details in attached base business 2001 tactical plan

The overall tactical budget for the Schizophrenia/Base business is \$25.55 MM.

Medical Marketing Key Programs/Tactics

Several clinical publications/new studies will be critical to the success of the RISPERDAL business in 2001 and beyond. They fall under key strategies as follows:

Differentiate RISPERDAL from the Competition

- RISPERDAL vs. Olanzapine study (Conley, RIS-USA-112) submitted to AJP
- Relapse Prevention study (Csernansky, RIS-USA-79) submitted to NEJM
- New Multicenter trial examining switching data from other APS to RISPERDAL – trial to begin 1Q01'

Protect and Expand Reach/Partnerships with Key Customer Base

- RISPERDAL use in Conduct Disorder (Aman, RIS-USA-93 and Findling, RIS-USA-97) manuscript in process
- New Multicenter trial examining RISPERDAL use in the Acute Setting (RIS 235) trial began Q400'

Base Business Key Programs/Tactics

Key 2001 medical education programs in support of Base business 2001 strategies: Differentiate RISPERDAL from the Competition, and Protect and Expand Reach/Partnerships with Key Customer Base, are as follows:

CME Teletopics	4 Programs (16 dates each)
CME Distance Learning Network	5 Programs
Promotional Dinner Programs	770 Programs
Speaker Training	200 attendees
Virtual CD-ROM Promo Program	5000 copies
Peer to Peer Roundtable Meetings	37
Regional CNS Advisory Forums	6
CME Audioconference (Conduct)	1
Acute Care Guidelines	1
Zeldox Destruction Plan	Multiple targeted tactics
Diabetes Advertorial	1
Diabetes Awareness Campaign	Multiple targeted tactics
CNS Advisory Forums	18

Reimbursement Key Programs/Tactics

Proactively Maximize Cost and Reimbursement Opportunities

As reimbursement issues become more prevalent, the Public Health Systems and Reimbursement Team (PHS&R) is expanding in size (5 additional positions), and will focus on several tactics focusing on four key areas: the VA system, medicaid, corrections and state mental health. Advisory boards in each of these areas have been planned. The Department of Corrections will be a particular area of focus for the reimbursement team. National Criminal Justice Advisory boards held last year will be followed up with regional ad boards in 2001, with specific tactics, such as CMS programs geared for a corrections audience. Furthermore, in California, where corrections facilities represent a significant dollar opportunity, the reimbursement manager will spend 60% of their time devoted to this segment of the business. Lastly, MUE's and DUE's are planned for institutions such as prisons and corrections systems. The Performance Guarantee Program will continue in 2001. Ten CME public sector forums have been planned. Several live satellite symposia are planned for the VA system that will take a closer look at issues such as atypicals and diabetes that greatly affect these patient populations. Please see the reimbursement tactical plan for full details on these, and other key tactics.

Salesforce Key Programs/Tactics

Maximize Salesforce Impact

In order to maximize salesforce impact, the field will be undergoing a realignment and expansion in the first quarter of 2001. This will allow the CNS salesforce to have better coverage in institutions, IMDs, clinics and private practices. Specific institutional marketing tactics have been put in place in order to better maximize the impact of Janssen I reps in their institutional accounts. In addition, the sales training team will begin to utilize the internet to expedite training of all representatives. Lastly, together with the marketing team, the CNS salesforce will be implementing the "Adopt a Doc" program, designed to increase Janssen's relationships with key thought leaders, prescribers and institutions.

New Formulations

Finally, the RISPERDAL franchise has two new formulation sNDAs planned for 2001. The first submission will be Quicksolv (0.5, 1 and 2 mg tablets) which is a rapidly dissolving formulation of RISPERDAL. The two most important opportunities for Quicksolv are the acute setting and the elderly population. Quicksolv will be an important introduction as it will allow us to remain competitive with Lilly's rapidly dissolving formulation of Olanzapine, Zydys, launched earlier in 2000.

The second submission will be Microspheres, which is a long acting injectable formulation of RISPERDAL that can be injected every two weeks. RISPERDAL will have a major advantage being the first to market this type of formulation amongst the atypicals. The largest area of opportunity for Microspheres is schizophrenia with a portion of the business also coming from bipolar disorder.

VIII. SUCCESS PREDICTORS:

- Destroy Zeldox launch impact on our business.
- Stop Seroquel growth.
- Drive RISPERDAL as the antipsychotic offering the best balance of efficacy and safety
- Significantly increase diabetes awareness with selected atypicals; make this a part of the basis for choosing RISPERDAL
- Neutralize perception of higher EPS and TD versus other atypicals
- Heighten awareness of cardiac issues with Zeldox
- Optimize data generation and dissemination
 - publish key studies and drive secondary analysis
 - disseminate key studies under WLF

- execute new trials: acute, switching, head-to-head
- JRF execution of future research, indications and label changes
- Support pediatric, acute medical education

2001 LTC/GERIATRICS

BUSINESS PLAN

I. **EXECUTIVE SUMMARY:**

Atypical antipsychotics are commonly prescribed for elderly patients who exhibit psychotic symptoms (delusions, paranoia, and hallucinations) as well as disruptive behaviors that interfere with needed care. The atypicals are a more attractive option compared to the conventionals, whose side effect profiles are very problematic, particularly to the vulnerable elderly patient population. While the brand's marketing focus has been in psychotic symptoms of dementia, we believe that there are opportunities in 2001 to expand into other mental illnesses of the elderly, such as psychosis w/o dementia, schizophrenia, Parkinson's Disease and others.

There are diverse treatment settings within geriatrics – nursing homes, Assisted Living, Community Mental Health Centers as well as home-based care. Within each setting a different mix of prescribers and influencers are involved; including psychiatrists, primary care physicians, geriatricians, neurologists and nurse practitioners. Influencers in our market include consultant pharmacists, directors of nursing, nursing staff, caregivers, and regulators. The needs of all these segments must be considered and will be addressed in our strategic and tactical plan for 2001.

In LTC/geriatrics market RISPERDAL is the market leader, more than one third of all antipsychotic prescriptions written for the elderly are for RISPERDAL. In dementia, RISPERDAL has achieved a significant leadership position commanding nearly half of the prescriptions in this market.

It should be noted our competition is aggressively expanding into this marketplace. Eli Lilly and Astra-Zeneca have had a strong presence at medical meetings and have increased their promotional activity during the past year. As a result both have made market share gains. Pfizer, a recognized leader in LTC (Aricept, Zolof) will introduce Zeldox in Q101 and we need to prepare for the potential impact of Zeldox despite limitations with its anticipated cardiac safety profile.

Our goals for 2001 are to increase RISPERDAL leadership in geriatrics. The brand will achieve their goals by implementing tactics against 4 key strategies: 1) strengthen our efficacy/safety positioning; 2) expand into additional elderly markets, 3) expand reach and educate a diverse audience, and 4) effectively position and maximize RISPERDAL & REMINYL.

The brand has several significant initiatives in our 2001 tactical plan. For example there will be a focus on broadening the perception of the benefits of RISPERDAL in other elderly diseases; implementation of non-rep mediated tactics to ensure expanded reach as well as re-enforce messages to current called on physicians. We will introduce RISPERDAL to new customers – such as Neurologists, Family Practice Residents, and Nurse Practitioners. We will conduct regional advisory boards in order to target and more effectively penetrate key local markets. These are just a few of the specific programs and tactics outlined in this plan and available in more detail in our expanded tactical plan.

Several success predictors must be driven forward to optimized RISPERDAL business in 2001.

- 1) Execution of new studies & dissemination of clinical data that at a minimum match the output of our competitors;
- 2) Psychosis in Alzheimer's disease indication trials (RIS-232/INT-83) remain on timelines;
- 3) Drive alignment and focus around the key issues, strategies and tactics among EC, CNS I-Reps, LTC, MSLs, OMP SLs, Medical Affairs, Sales Training, & JRF;
- 4) Strengthen label related to geriatrics;
- 5) Maximize FDAMA; and
- 6) Maximize RISPERDAL/REMINYL positioning & synergies.

II. SITUATION DIAGNOSTIC/ANALYSIS:

There has been significant growth (+24% MAT9/00) in the use of atypical antipsychotics in geriatrics/LTC. Several factors are driving this growth, including:

- Demographic trends shifting toward an aging population
- Increased awareness of dementia and acceptance to appropriately manage associated symptoms
- Use of antipsychotics, particularly atypicals, which are increasingly recognized as the standard of care for patients struggling with dementia and its associated behaviors and symptoms
- Declining use of conventionals due to concerns about safety, EPS and TD

Use of conventional antipsychotics continues, however it is declining more rapidly in geriatrics (25% share in dementia) compared to the market overall. In some indications, such as elderly psychosis the use of conventionals remains high.

The brand's promotional focus has been in psychotic symptoms associated with dementia, as this is the largest segment of elderly in whom antipsychotics are used. We do believe there are other opportunities in 2001 to use appropriately and effectively use our clinical data to expand use of RISPERDAL in other serious mental illnesses in the elderly, such as psychosis w/o dementia, schizophrenia, Parkinson's Disease and others.

Many elderly patients are placed in nursing homes and other extended care facilities due to their illnesses and/or associated behavioral disorders so these facilities remain an important target market for RISPERDAL. Within the nursing home setting, the important prescribers are the consulting psychiatrists, medical directors, attending physicians and nurse practitioners. Other influencers include the consultant pharmacists, Directors of Nursing and the nursing staff. Many nursing homes are struggling to survive within a highly structured regulatory and reimbursement environment. Organizations that do survive are often plagued with reduced reimbursement, low census and a high turnover among an often inadequately trained staff.

Assisted Living Facilities, Community Mental Health centers and even home-based care are emerging as alternatives to nursing homes and are important target segments for RISPERDAL. There is clearly an opportunity for RISPERDAL to strengthen our focus on the outpatient setting and to more effectively and appropriately target family practice, geriatricians, nurse practitioners, neurology and psychiatry.

Both family caregivers and professional caregivers (for example, the certified nurse assistant in a nursing home) are often on the front line in dealing with resident's symptoms. They often communicate the behaviors of a patient to the prescriber. Caregivers are an important audience to educate on such issues as symptom recognition and how to effectively manage these symptoms using both pharmacological and non-pharmacological treatments.

Our primary competitors, Zyprexa and Seroquel continue to make inroads in the geriatric marketplace.

Zyprexa in particular has been very active; a few key highlights:

- ✓ Zyprexa's second double-blind placebo controlled study in dementia authored by Street *et. al.* was recently published (*Archives of General Psychiatry, October 2000 issue*) and it is already being used by Lilly aggressively in the field via WLF.
- ✓ Lilly has recently expanded its field force to a total of 160 LTC representatives and is recruiting consultant pharmacists. They have also redirected up to 1300 PCP representatives in support of Zyprexa. This has expanded Zyprexa's reach into this community.
- ✓ Lilly is actively pursuing a claim for the use of Zyprexa in dementia/Alzheimer's Disease and our market intelligence indicates they may likely be up to 6 or more months ahead of our timelines.

Seroquel has been particularly aggressive in the elderly market.

- ✓ They are making significant marketing noise through posters and presentations of re-analyzed data sets.

- ✓ Astra is having an impact with prescribers focusing on the sedating properties of Seroquel, which is viewed by some as an advantage.
- ✓ Seroquel has only minimal efficacy but is focusing on an overall perceived safety profile - this focus has made it an increasingly attractive agent.
- ✓ Among neurologists Astra has created some inroads seeking support for use in the management of psychosis associated with Parkinson's Disease. OMP's Neuroscience representatives have been calling on neurologists since early October and are expected to assist in blunting any impact and maximize the RISPERDAL opportunity with neurologists.
- ✓ Additional tactics with OMP are planned for 2001.

Zeldox most likely will enter the market in 1Q01 with an indication for the manifestation of psychosis in schizophrenia.

- ✓ To date, clinical data on Zeldox in geriatrics has neither been postered or published.
- ✓ Since the product is associated with QTc interval prolongation this safety precaution will likely be a deterrent to usage in the vulnerable elderly patient population.

III. PRODUCT PERFORMANCE SUMMARY:

RISPERDAL remains the #1 prescribed antipsychotic in the elderly market with a current NDTI market share of 34%. In dementia, the market share is 49% and the gap between the other atypicals and conventional agents is significant. RISPERDAL in LTC/geriatrics is currently the #2 indication for the overall molecule and is expected to maintain this position. With the possible addition of other indications/uses to our promotional mix in 2001 the importance of the elderly market to RISPERDAL will continue to be significant.

The RIS-63 (Katz) study (published February 1999) has been a powerful and convincing study supporting RISPERDAL use in patients with dementia. In July of 2000 the long-term extension to RIS-63, RIS-70 (Jeste) was published. Both these articles have been approved for dissemination via FDAMA and we begin dissemination in February 2001. These two studies and others form the foundation of the brand's medical education.

The launch of the J&J LTC group has enabled us to have an effective reach into the LTC pharmacy provider market. Our ElderCare sales force has been effective despite its limited reach into our target audience. Both teams have consistently and effectively delivered our critical messages on the benefits of RISPERDAL to our target audiences - nursing homes, consultant pharmacists, primary care physicians and psychiatrists.

All competitors have increased their promotional activities toward prescribers in this market segment. Astra and Lilly have begun to recognize the importance of this market and are deploying significant resources against it.

IV. SWOT ANALYSIS, KEY ISSUES:

An assessment of RISPERDAL's strengths and weaknesses in the current marketplace reveals the following:

Strengths

- ElderCare: Janssen's #1 strategic objective
- Efficacy/safety data (RIS-63 & RIS-70)
- Continued market leadership
- J & J LTC/ElderCare team; Expansion
- Performance based contracts
- Dosing flexibility and cost advantage

Weaknesses

- EPS liability
- Sub-optimal deployment against emerging customers (PCPs, Neuros, NPs)
- Lack of geriatrics/dementia data in label
 - Limitations in use of our clinical data and lack of comparative data

Opportunities

- New geriatrics markets (e.g., elderly psychosis)
- Residency Programs, Training Centers,
- Professional & Family Caregivers, State
- Surveyors & other influencers
- LTCPP Market Share Tier Programs
- Clinical/outcomes data
- Accelerate conversion of conventionals
- RIS/REM position/synergies
- e-business
- FDAMA submission of RIS-63 & 70

Threats

- Seroquel/Zyprexa: expanding geriatric focus
 - sales force, marketing & clinical
- Zeldox geriatric focus?
- ACHEIs/AC/AD positioning in behaviors
- Reimbursement environment:
- PPS/Medicare; Medicaid?
- RIS not first with indication

The key issues in 2001 for RISPERDAL in LTC/Geriatrics are:

- ✓ Increased competition from atypicals and other drug classes, i.e., ACHEIs, AC, and AD.
- ✓ Untapped market opportunities (e.g. elderly psychosis)
- ✓ Educational needs on appropriate use and benefits of atypicals not being met across diverse customer base
- ✓ Current labeling unfavorable
- ✓ RISPERDAL & REMINYL co-positioning

V. STRATEGIC OBJECTIVES:

Grow RISPERDAL leadership position in LTC marketplace.

Our positioning in the geriatrics marketplace has remained consistent: RISPERDAL has the best combination of efficacy and safety while providing needed dosing flexibility.

Our support for this positioning has been strengthened with the launch of a new effective promotional platform and wide acceptance of our lower dosage strengths (0.25mg and 0.5mg, launched August 1999).

Our core messages in the 2000 campaign are:

Outstanding Efficacy

- Significant improvement in psychotic symptoms and behaviors
- Improvement as soon as one week
- Efficacy maintained for one year

Excellent Safety Experience

- Low incidence of excessive sedation
- Benign anticholinergic profile

- Minimal EPS at recommended low doses
- Custom-Tailored Dosing**
- Available in 0.25 and 0.5mg dosage strengths as well as oral liquid formulation

VI. BUSINESS STRATEGY:

1. Strengthen efficacy/safety positioning vs. the competition and grow our leadership dominance in LTC/Geriatrics
2. Expand effectively into additional geriatrics markets
3. Expand reach/educate a diverse audience:
 - PCPs, Neurologists, NP
 - Training Centers (ADRC, GRECC/VA, Residency Programs)
 - State Surveyors
 - Professional and Family Caregivers
4. Effectively position and maximize RISPERDAL/ REMINYL

VII. KEY PROGRAMS AND TACTICS:

Strategy #1: Strengthen efficacy/safety positioning vs. the competition

Program	Volume/Description
Advisory Boards (Home Office)	9 programs
Regional Advisory Boards	9 programs
Speaker Training	250 physicians
CME Senior Care Seminars	1100 Programs (5 / Rep)
CME Distance Learning Network	1 Program
<u>CME Teletopics</u>	2 Programs (16 dates each)
Quality Indicator Program	Multiple tactics (symposia, SCS, Promotion)
LTC Pull-through	Market share targets

Other tactics include:

- Promotional platform
- Publications
- Medical Meetings/Symposia
- Medical Affairs
- FDAMA: Dissemination of published studies in dementia
- Label changes in dosing/precautions section of PI

Strategy #2: Expand effectively into additional geriatrics markets

Program	Volume/Description
Elderly Psychosis Program/ Parkinson's	Multiple tactics: DLN, CME web-based program, GMR website, posters, symposia

Strategy #3: Expand reach/educate a diverse audience

Program	Volume/Description
Primary Care Outreach	Multiple tactics: Target Prozac writers; SCS audiotape; Direct mail; AAFP Symposium,

NP/PA Symposium; Journal
supplement

Nurse Education
Neurology

Magic pen/training for CNAs
Multiple tactics: OMP
Neuroscience reps, promo
materials, SCS, Ad boards,
NIH consensus conference

Other tactics:

- CNS Summit
- Keystone 3
- AAGP Stepping Stones
- AAGP Training Directors Program
- Summer Research Institute
- Education initiatives: state surveyors, nurse practitioners, caregivers, nurses
- Residency Program (Primary Care/Geriatrics)
- AMDA Futures Program
- ADRC/GREC/VA Program
- Adopt-a-doc
- Assisted Living Pilot (Alterra)

Strategy #4: **Effectively position and maximize RISPERDAL/ REMINYL**

- SCS
- Advisory Boards
- Speaker Bureaus and Training
- Symposia/Enduring Materials
- Caregiver Education
- Sales Training/Preceptorships

VIII. SUCCESS PREDICTORS:

To be successful in this marketplace, certain things must happen. The brand team will play a key role in driving each of these success predictors:

- *Execution of new studies & dissemination of clinical data that at a minimum matches the output of our competitors*
- *Psychosis in Alzheimer's disease indication trials must remain on timelines*
- *Drive alignment and focus around the key issues, strategies and tactics by EC/CNS I-Reps/ LTC/ MSL/OMP SL/ Medical Affairs, Sales Training & JRF*
- *Strengthen label related to geriatrics*
- *Maximize FDAMA*
- *Maximize RISPERDAL/REMINYL positioning & synergies*

Sales Plan Summary

Long-Term Care / Janssen-ElderCare 2001 Business Plan - Highlights

After a very successful 2000, the LTC/EC teams are poised for another outstanding year in 2001. The expansion of the EC sales force to 135 representatives with the addition of 50 EC specialists will allow us to stay competitive in this market and regain our leadership position as the number one company in ElderCare.

The expansion and training is scheduled for completion by end of March 2001. This will expand our reach to 73% of the PCP APS 3 - 9 from 2,700 to 5,090. The call average is targeted for 7 per day, with a frequency of 12 calls per year on 90% of the key targets. RISPERDAL call activity by customer segment is summarized as follows:

	#Targets	Frequency
PC/IM	5,090	12.0
Med. Dir. & Attending Phys.	9,000	6.0
Psych Consultants	2,250	6.0
Psychs	2,932	12.0
VA NH Facilities	62	6.0
LTC Facilities NH	4,500	6.0

Working closely with the brand team the EC/LTC team will be utilizing among others - CME/CE accredited speaker programs, teletopics and advisory boards to accelerate growth for our key strategic brands.

Our efforts will be focussed on harnessing the power of technology to expand our reach and give us a distinct competitive advantage. Two major initiatives are the Dr to Patient web hosting program and the launch of Janssen-ElderCare.com. Differentiating the EC/LTC teams from competitors will continue to be the focus throughout 2001.

Human resources development and improving the standards of performance to ensure that over 65% of the sales force is in stage II of the standards of leadership will be a priority for the management team.

To stay competitive in this market place the LTC group will work on creative contracting programs to curtail the intense competitive activities and stay ahead.

2001 US AFFECTIVE DISORDERS

BUSINESS PLAN

I. EXECUTIVE SUMMARY:

Bipolar disorder is one of the most significant opportunities within the Affective Disorders market. Johnson & Johnson is in the enviable position of having two products -- RISPERDAL® (risperidone) and REDACTED -- in its CNS franchise with significant potential in this market.

Today the bipolar market remains dissatisfied as evidenced by the growth of new and novel compounds that are used to treat this disorder. Failure of one medication to satisfy the needs of this market is particularly evident as combination therapy with several medications is commonly employed to treat this complicated disease which has at least three phases of illness -- acute mania, bipolar depression, and the maintenance phase.

In the coming years, Johnson and Johnson will be in the unique position of having both RISPERDAL and REDACTED approved for the treatment of bipolar disorder. Given the current treatment paradigm of an anticonvulsant (AED) and an antipsychotic in the early phases of the disease, Janssen Pharmaceutica in conjunction with Ortho-McNeil Pharmaceuticals (OMP), plan to maximize the use of both products as the treatment combination of choice in all phases of bipolar disorder. Furthermore, in addition to bipolar depression, Janssen will assess and pursue as appropriate the development of RISPERDAL in refractory depression.

J&J's success will depend upon the ability of both compounds to prove that they are independently safe and effective in treating all phases of bipolar disorder. It will then be critical that Janssen demonstrate that the combination offers superior efficacy, safety, and tolerability advantages over other combinations. Currently, separate clinical development programs are underway. RISPERDAL is under JRF clinical development with input from JPI, while REDACTED RED Final commercialization responsibility for both products in affective disorders resides with JPI.

RISPERDAL, Janssen's prescription-leading atypical antipsychotic, has clinical data supportive of its outstanding efficacy and tolerability in acute mania. In June of 2000, an sNDA for acute mania had been planned for RISPERDAL. This sNDA was to include two pivotal studies. The first, RIS-USA-102, was a successful 'add-on' study which evaluated RISPERDAL's efficacy in combination with a mood stabilizer as compared with a mood stabilizer alone. The second, RIS-INT-046, was a similarly designed international version of RIS-USA-102. The primary difference between the two studies was that, unlike RIS-USA-102, RIS-INT-046 allowed the use of carbamazepine (now known to lower RISPERDAL blood levels) as one of the mood stabilizers. RIS-INT-046 narrowly missed clinical significance in its primary endpoint.

RISPERDAL has also demonstrated efficacy in treating depressive symptoms in various small pilot studies conducted outside of Janssen. Efficacy in remitting depressive symptoms was also observed when analyzing sub-populations of pivotal clinical trials (e.g. patients with schizophrenia and schizoaffective disorder). In addition, according to IMS Health NDTI data, depression constitutes 16% of overall RISPERDAL use. The current use of RISPERDAL to treat depressive symptoms coupled with depressive efficacy indicators from pilot clinical trials, led the Affective Disorders franchise team to evaluate the commercial viability of RISPERDAL as an adjunct treatment for both bipolar depression and refractory depression.

Due to the delay in the RISPERDAL sNDA submission for acute mania, the clinical development plan has been enhanced and now includes three additional double-blind, placebo-controlled 'monotherapy' studies for RISPERDAL in acute mania. These studies are expected to be completed and submitted with RIS-USA-102 in an sNDA in 2Q02, with anticipated approval in 2Q03. The FDA has informed Janssen that, assuming one of the additional monotherapy studies is successful, RISPERDAL would be awarded an 'add-on' and 'monotherapy' indication for the treatment of acute mania.

REDACTED

REDACTED

Despite the independent phase III clinical programs for RISPERDAL and REDACTED all commercialization (including the investigator-initiated programs) will be geared towards positioning both products as *the ideal treatment combination in all phases of bipolar disorder*.

Overall, the success of the co-positioning will depend on 7 critical factors:

- Increased clinical data in all phases of bipolar disorder
- Increased medical education and data dissemination
- Leverage of existing positive perceptions for both products
- Enhanced coordination/communication between affective and schizophrenia segments
- Accelerated program for RISPERDAL in depression
- Co-administration data confirming tolerability, safety, and efficacy
- Market acceptance of long-term tolerability as a leading indicator of successful treatment

The Affective Disorders 2001 tactical plan is designed to lay the foundation for all 7 critical success factors. It is essential that we prepare the market place for the approval of these products with data through approved communication venues that will build physician confidence and experience with these two valuable medications.

II. SITUATION DIAGNOSTIC/ANALYSIS:

The US bipolar market is currently valued at over \$1.4 billion [IMS Health, NDTI & Retail & Provider Perspectives, 1999]. With the addition of several new therapeutic options, the dollar volume of the market has been growing at about 20% annually over the past few years. In all phases of bipolar disorder, antipsychotics represent about 17% of treatment, AEDs represent about 33%, and lithium comprises 16% of drug use. In general, the bipolar market is highly dissatisfied as evidenced by the fact that approximately three-quarters of treated patients are prescribed some form of combination pharmacotherapy and combinations vary greatly. [Adelphi Patient Study, 1999].

Currently, US-based physicians most commonly prescribe a mood stabilizer -- either an anti-epileptic drug (AED) or lithium -- as first-line treatment of **acute mania**. In about 70% of patients, an adjunctive antipsychotic is added in the acute phase [Adelphi Patient Study, 1999]. In less than 10% of acute manic patients, an antipsychotic is used alone as monotherapy. The antipsychotic may be continued (with a mood stabilizer) in the **maintenance** phase of treatment in about 35% of patients [Adelphi]. As a group, psychiatrists account for approximately 82% of the total bipolar prescriptions [NDTI, MAT 9/00].

Antipsychotics:

Among antipsychotics, RISPERDAL's share of bipolar patients is 27% versus Zyprexa's share of 36% and Seroquel's share of 13% [NDTI, MAT 9/00]. Following the approval of Zyprexa for acute mania in March 2000, overall Zyprexa share increased substantially (+4 share points) and reversed a several month share decline due to concerns of weight gain and diabetes. Prior to Zyprexa's mania approval, RISPERDAL bipolar share had been flat since the launch of Zyprexa in late-1996. Encouragingly, Zyprexa's labeling has had some 'halo' effect on RISPERDAL's bipolar share which is reflective of the 'expectation of efficacy' clinicians have for the class of atypical antipsychotics.

Its important to note, currently, Zyprexa is the *only* atypical antipsychotic indicated for the short-term treatment of acute mania. However, in addition to RISPERDAL, Seroquel and Zeldox both have postered or published acute mania efficacy data. In November 2000, AstraZeneca announced that there are four Phase III trails underway for Seroquel in bipolar disorder.

REDACTED

The competitive landscape in agents indicated for bipolar disorder will increase substantially. Zyprexa has an extensive clinical development program in place that is expected to generate an approval for bipolar maintenance in 2003 and bipolar depression in 2004. Lilly has aggressively targeted Depakote head-to-head in clinical trials and is expected to continue to position Zyprexa as a more effective and better tolerated 'mood stabilizer'.

Seroquel and Zeldox are expected to receive acute mania indications in 2002 – 2003. Additionally, Pfizer is expected to continue to fully leverage the depression data of Zeldox to differentiate the product. An increase in clinical development for RISPERDAL will be critical during the next two years as 2003 labeling for acute mania will likely lag several competitors.

III. PRODUCT PERFORMANCE SUMMARY:

Differentiating RISPERDAL from other agents while establishing its role in the treatment of bipolar disorder was the goal in 2000. Market research (quadrant analyses) conducted in July 2000, indicated RISPERDAL was at least as well perceived as Zyprexa on key acute mania efficacy and safety attributes as Zyprexa. Full product *differentiation* has not yet been achieved due to the promotional volume caused by Zyprexa's approval for acute mania in 1Q01.

2000 Critical Success Factors

- Quality and timing of RIS-USA-102 / INT-046 studies
- Increase opinion leader support
- Increase medical education share of voice

Accomplished

Mixed results, sNDA delayed
Speaker's bureau increased
Accomplished, greater increase in '01

2000 Lessons Learned for 2001

- Battleground is based on mood stabilization... not monotherapy
- Need broader reach via medical education
- Inadequate synergy with schizophrenia team and OMP
- RISPERDAL **REDACTED** co-positioning needs development
- Seroquel is a formidable competitor
- Some antipsychotic schizophrenia perceptions 'carry over' to bipolar market

IV. SWOT ANALYSIS:

RISPERDAL - Affective Program

Strengths

- Add-on data supports present treatment paradigm
- Low weight gain/somnolence vs. OLA
- Low diabetes vs. OLA
- Lower cost than OLA / SER
- Well-known antipsychotic profile

Opportunities

- Dissemination of RIS-102 via FDAMA
- Dissemination of Segal data via FDAMA
- Capitalize on OLA diabetes profile
- Highly unsatisfied market
- Depression data (bipolar & unipolar)
- OLA /**RED** PK (interaction) data

Weaknesses

- Lack of fully developed clinical plan
- Will be 2nd/3rd indicated APS
- Sales force unable to promote
- Perceived EPS/TD liability
- Bipolar dosing not established

Threats

- Significant increase in OLA promotion
- Bipolar, Zydys, IM
- RIS /**RED** PK (interaction) data
- **RED** remedies OLA weight gain
- Lilly APS/MS combination patent
- Zeldox (ziprasidone) affective data
- OLA labeling as "psychotropic"

REDACTED



KEY ISSUES:

1. Increasing competitive intensity

- RIS acute mania labeling lags Zyprexa by 3+ years
- Zeldox and Seroquel have fully developed acute mania clinical programs

2. RISPERDAL **REDACTED co-positioning not established**

- **REDACTED**
- Lack of RIS /**RED** interaction or combined efficacy data

3. Inadequate Phase IV and EMRP data availability and funding

- RIS EMRP has failed to produce timely affective data

- RED EMRP has non-competitive volume of bipolar projects
- Phase IV projects limited to re-analyses of existing data

V. 2001 STRATEGIC OBJECTIVES:

The objective for 2001 is to *increase adoption* of RISPERDAL as an antipsychotic with mood stabilizing properties in all phases of bipolar disorder. RISPERDAL's mood stabilizing perceptions will be based on its efficacy profile in mania and depression and its long-term tolerability.

REDACTED

VI. POSITIONING AND STRATEGIES:

Positioning:

Since J&J has a true bipolar franchise, with both an antipsychotic and an anti-epileptic drug, the positioning of the franchise is, ***TOPAMAX and RISPERDAL is the ideal mood stabilizer/atypical antipsychotic combination for the treatment of bipolar disorder*** due to:

- The superior efficacy and rapid onset of action of both drugs in acute mania
- The efficacy of RISPERDAL in depressive symptoms

REDACTED

- The long-term safety and tolerability of both agents

Core Messages:

The core messages supportive of the co-positioning are that the use of both TOPAMAX and RISPERDAL matches the well-established treatment paradigm of combination therapy. Additionally, both TOPAMAX and RISPERDAL have documented clinical efficacy in the treatment of acute mania. The unique and non-competing mechanisms of action for both products are synergistic. Both products have fast onset and a sustained effect. Weight gain has been a major issue in the long-term treatment of bipolar disorder. RISPERDAL has substantially lower weight gain than Zyprexa REDACTED

REDACTED

Core Strategies:

1. Differentiate RISPERDAL as the preferred antipsychotic in the treatment of bipolar disorder.

The *short-term* approach to this strategy will be to create data via medical affairs studies (phase IV, investigator-initiated, and outcomes) which leverage RISPERDAL perceptions in core symptoms and raise awareness of long-term safety and tolerability.

The long-term approach will be to establish a well-developed and accelerated JRF-driven clinical development plan for label submission.

REDACTED

3. Position RISPERDAL and TOPAMAX as the optimum treatment combination for bipolar disorder.

Although each product is independently supported via a clinical development program, the combination will be marketed with a better therapeutic outcome together than either could achieve separately. Specific co-positioning *refinement* will be conducted through a series of advisory boards and market research.

4. Determine the clinical / financial viability of commercializing RISPERDAL for add-on therapy in depressive disorders.

Beyond bipolar disorder alone, RISPERDAL has already revealed evidence of efficacy in affective subscales and meta-analyses of existing clinical trials. Advisory and forecast work will determine the risks and rewards involved with a full depressive disorder clinical program.

VII. KEY PROGRAMS AND TACTICS:

The tactics for 2001 build on several lessons learned from 2000 tactical execution. Most importantly, potential vendor synergies (where similar programs were supported) were not fully leveraged between the affective and schizophrenia marketing teams. Programs in 2001 will utilize as few unique vendors as possible between the two teams. This creates negotiating leverage on price and simplifies field sales force program execution. Lastly, a variable cost-per-attendee analysis led to the discontinuation of more costly CME support and an increase in more economical programs.

The overall tactical budget for the affective program is \$12.5M (\$7.0M from RISPERDAL PMEs, \$3.5M from CNS Medical Marketing REDACTED)

Strategies: (1) Differentiate RISPERDAL and (2) Establish TOPAMAX in Bipolar Disorder

Several clinical publications will be critical to the success of these strategies. Among these critical publications is the add-on study (RIS-USA-102), the combination of both add-on studies (RIS-USA-102 and RIS-INT-046), a methodology paper for REDACTED, and a variety of sub-analyses of affective measures from existing studies. In addition, a variety of medical education program formats for affective disorders (bipolar disorder and refractory depression) will be supported in 2001:

Program	Volume
CME Dinner Programs	770 Programs (2 / CNS Rep)
CME Audioconference	2 Programs (16 dates each)
CME Teletopics	2 Programs (16 dates each)
CME Distance Learning Network	2 Programs (16 dates each)
RIS-USA-102 Reprints (FDAMA)	120k reprints (400/rep)
Segal Study Reprints (FDAMA)	120k reprints (400/rep)

Strategies: (3) Define optimum RISPERDAL / TOPAMAX Positioning in Bipolar Disorder and (4) Determine viability of commercializing RISPERDAL in Depressive Disorders

The overall positioning will focus on establishing RISPERDAL and TOPAMAX as the ideal treatment combination of choice in bipolar disorder. Specific refinement of the positioning (e.g. synergistic tolerability and efficacy aspects) will be aided through a series of advisory programs. Additionally, the expansion of the RISPERDAL clinical program to include depression will be assessed through the same tactics:

Program	Volume
National Advisory Board (1)	15 Top-tier academic KOLs

Bi-Regional Advisory Boards (3) 150 HVP KOLs
Clinical Consultants (3) Keck, Sachs, Calabrese

VII. SUCCESS PREDICTORS:

The success of the affective disorders program will depend on several critical factors:

- Increased reach and frequency of medical education programs (vs. 2000)
- Accelerate and maximize affective data generation
- Capitalize on existing positive perceptions of RISPERDAL **REDACTED** (e.g. rapid onset, efficacy in core symptoms, broad spectrum efficacy, etc.)
- Create and maximize marketing efficiencies and integration between franchise segments
- Accelerate program for major depression (determine filing or publication approach by 1Q01).

**RISPERDAL® SUMMARY
APPENDIX 1**

	1998	1999	2000 EST.	2001 Forecast
Market Size (\$MM)	\$2,459	\$3,201	\$3,931	\$5,008
% Growth		+30.2%	+22.8%	+27.4%
Net Trade Sales (\$MM)	\$695	\$892	\$1,083	\$1,207
% Growth		+28.3%	+21.4%	+11.4%
Volume TRx (000's)	5,430	6,662	8,555	9,454
% Growth		+22.7%	+28.4%	+10.5%
Volume NRx (000's)	2,929	3,656	4,724	4,521
% Growth		+24.8%	+29.2%	-0.04%
Market Share (%)				
TRx	23.7%	26.5%	30.0%	29.8%
Dollars	32.1%	32.2%	32.3% (YTD 11/00)	28.8%
Distribution of Business by Indication (Drug Uses %)				
Schizophrenia	25.5%	23.3%	25.9%	
Bipolar Disorder	14.5%	13.8%	17.2%	
Depression	16.6%	19.3%	17.1%	
Dementia	11.2%	14.9%	10.9%	
Psychoses-Other	10.9%	7.9%	9.6%	
Anxiety	3.5%	5.9%	4.9%	
Distribution of Business by Specialty (NRx %)				
PCP	17.0%	17.0%	16.8%	
PSYCHS	73.0%	72.6%	72.5%	
NEUROLOGY	2.1%	2.1%	2.0%	
Average Price Per Unit (AWP)				
RISPERDAL – 0.25 MG		\$2.53	\$2.66	
RISPERDAL – 0.5 MG		\$2.53	\$2.66	
RISPERDAL – 1 MG	\$2.32	\$2.53	\$2.66	
RISPERDAL – 2 MG	\$3.87	\$4.22	\$4.42	
RISPERDAL – 3 MG	\$4.56	\$4.98	\$5.22	
RISPERDAL – 4 MG	\$6.01	\$6.56	\$6.88	
Zyprexa – 2.5MG	\$4.56	\$4.81	\$5.00	
Zyprexa – 5 MG	\$5.39	\$5.69	\$5.91	
Zyprexa – 7.5 MG	\$5.39	\$5.69	\$6.20	
Zyprexa – 10 MG	\$8.19	\$8.64	\$8.98	
Zyprexa – 15 MG		\$12.93	\$13.43	
Zyprexa – 20 MG			\$17.95	
Zyprexa – 5 MG Zydys			\$7.03	
Zyprexa – 10 MG Zydys			\$10.08	
Seroquel – 25 MG	\$1.26	\$1.36	\$1.42	
Seroquel – 100 MG	\$2.29	\$2.48	\$2.58	
Seroquel – 200 MG	\$4.50	\$4.68	\$4.87	

**RISPERDAL®
COMPETITIVE OVERVIEW
APPENDIX 2**

	1998	1999	2000	2001 Forecast
Average Price Per Day (AWP)				
<u>Overall</u>				
RISPERDAL			\$5.60	
Zyprexa			\$10.36	
Seroquel			\$7.18	
<u>Schizophrenia</u>				
RISPERDAL			\$7.78	
Zyprexa			\$13.09	
Seroquel			\$9.80	
<u>Bipolar Disorder</u>				
RISPERDAL			\$5.20	
Zyprexa			\$9.73	
Seroquel			\$6.90	
<u>Dementia</u>				
RISPERDAL			\$3.90	
Zyprexa			\$7.34	
Seroquel			\$2.63	
IMS Sales (\$MM)			(YTD 11/00)	
RISPERDAL	\$790	\$1,032	\$1,164	
Zyprexa	\$1,103	\$1,487	\$1,693	
Seroquel	\$90	\$221	\$367	
Clozaril	\$253	\$251	\$215	
Conventionals	\$223	\$209	\$165	
Dollar Market Share (%)			(YTD 11/00)	
RISPERDAL	32.1%	32.2%	32.3%	
Zyprexa	44.8%	46.5%	47.0%	
Seroquel	3.7%	6.9%	10.2%	
Clozaril	10.3%	7.9%	6.0%	
Conventionals	9.1%	6.5%	4.6%	
TRx Market Share (%)				
RISPERDAL	23.7%	26.5%	30.0%	
Zyprexa	17.6%	21.4%	23.5%	
Seroquel	2.4%	5.5%	8.9%	
Clozaril	9.1%	8.2%	7.9%	
Conventionals	47.3%	38.3%	29.6%	

**RISPERDAL®
COMPETITIVE SPEND
ATTACHMENT 3**

	Sales Force # Reps # Contacts	Extended Units (Share of Sample Days of Therapy)	Med Ed (\$)	Journal (\$)	DTC (\$)
RISPERDAL	375 CNS (reflects expansion) 135 Eldercare (reflects expansion) 100 OMP • 172,000 contacts (1999) • 184,000 contacts (YTD 11/00)	9.97 MM (YTD 11/00) (33.2% Share)	\$8.61 MM (1999) \$8.05 MM (YTD 9/00)	\$2.21 MM (1999) \$1.88 MM (YTD 11/00)	N/A
Zyprexa	365 Neuroscience 100 Hospital 1300 Field - PCP • 164,000 contacts (1999) • 203,000 contacts (YTD 11/00)	12.07 MM (YTD 11/00) (48.2% Share)	\$7.75 MM (1999) \$7.50 MM (YTD 9/00)	\$2.05 MM (1999) \$1.78 MM (YTD 11/00)	N/A
Seroquel	500 CNS 70 Contract • 90,000 contacts (1999) • 95,000 contacts (YTD 11/00)	8.46 MM (YTD 11/00) (18.6% Share)	\$5.03 MM (1999) \$4.53 MM (YTD 9/00)	\$1.41 MM (1999) \$1.68 MM (YTD 11/00)	N/A

Med Ed data pulled from Scott Levin PMEA Audit
Sales force data from Scott Levin Sales Force Structures and Strategies (4Q 2000)
Samples and journal data from IMS Health

**RISPERDAL®
MARKET RESEARCH
APPENDIX 4**

Market Research:

- Tracking the Competition/Understanding the antipsychotic marketplace
- Defend against ziprasidone launch
- Support competitive Marketing efforts
- Identify / drive new business opportunities

2001 Market Research Plan:

Objective	Rationale	Target	Timing (start/finish)
Tracking the Competition			
Ziprasidone Early Adopter Exploratory	Determine motivators for trial among earliest ziprasidone adopters	Ziprasidone lead users	Q1
Ziprasidone Imagery Tracking	Early read quantification of Ziprasidone imagery v. competition	Top decile Psychs	ONGOING
Annual Drug Perceptions Study	Compare brand imagery to competition	Top decile Psychs	Q1
Rep Message Tracking Studies (2 Waves)	Compare physician recall of RIS details to competition	Janssen target Psychs	Q2/Q4
DTW Promotional Materials Tracking	Monitor competitive promotional messages	All CNS	ONGOING
MMI Schizophrenia Market Overview	Update brand usage and imagery information	Psychs	Q3
APA Tracking Study	Monitor product use/switching preference over time	Psychs	Q1
Competitive Marketing			
Safety Exploratory/Journal Ad Development (3 Waves)	Develop promotional materials to capitalize on competitive weaknesses (or defend RIS weakness) Diabetes, QTc, EPS/TD	Janssen target Psychs	Q1-3
Quant. Journal Ad Testing ("Tip-In") 2 Ads	Determine recall, communication, and persuasive power of new journal ads	Janssen target Psychs	Q2/Q4
Advertising Awareness Tracking	Determine longevity, continued impact of journal ads	Janssen target Psychs	Q2
Develop New Sales Aids/Slim Jims/Flashcards (Acute, Base, Competitive)	In-depth interviews to develop new sales materials	Janssen target Psychs	Q1/Q3

Objective	Rationale	Target	Timing (start/finish)
New Business Opportunities			
Microspheres Administration Study	Understand RN use and reaction to microspheres format	Psych RN's	Q1
Depot Positioning And Pricing Studies	Develop strongest promotional messages for microspheres/Determine optimal price range for microspheres	Top decile Psychs	Q2
U.S. Depot A&U	Understand current depot market usage dynamics to expand market for Microspheres launch	All Psychs	Q1-2
Quicksolv Positioning And Pricing Study	Develop strongest promotional messages for Quicksolv/Determine optimal price range for Quicksolv	Top decile Psychs	Q1
New Forms Message Testing	Develop messages/concepts to support launch of QuickSolv and Microspheres	Top decile Psychs	Q3-4
E-POC In-Depth Interviews	Determine key selling points of E-POC device to psychiatrists	Janssen target Psychs	Q2

**RISPERDAL®
MARKET RESEARCH
APPENDIX 4**

Market Research:

- Develop plan to differentiate RISPERDAL as preferred agent in the treatment of bipolar disorder
- Pre-determine how to position RISPERDAL + TOPAMAX as optimum treatment combination for bipolar disorder pending FDA approval for indications
- Begin development of positioning for TOPAMAX as broad spectrum mood stabilizer in conjunction with clinical plan process

2001 Market Research Plan:

Objective	Rationale	Target	Timing (start/finish)
Differentiate RISPERDAL			
Bipolar Depression Evaluation	Explore use of APS in the treatment of bipolar depression	Psychs	Q1
BPD Annual Perceptual Mapping	Assess overall perceptions of APS and MS in BPD	Psychs, PCPs	Q1
BPD A&U Tracking	Monitor physicians' A&U of APS and MS to treat BPD (Tx paradigm)	Target Psychs	Q1, Q3
Seroquel/Ziprasidone BPD Message Evaluation	Evaluate adoption of Seroquel/ziprasidone in BPD market by heavy users	Target Psychs	Q2
APA Bipolar Study	Track change in physicians' usage patterns in the treatment of BPD	Psychs	Q2
Adelphi 2001 Bipolar Disorder Study	Track BPD disease management trends and APS product assessments	Psychs	Q3
RISPERDAL / TOPAMAX Co-Positioning			
RISPERDAL / TOPAMAX Message Development	Develop optimal joint sales messages for RIS/TPX in psychiatry	Target Psychs	Q1
RISPERDAL / TOPAMAX Message Recall	Monitor physicians' recall and reaction to joint RIS/TPX sales message	Target Psychs	Q4
BPD Opportunity Assessment	Evaluate unmet medical need for APS and MS in various phases of BPD	Psychs	Q2
RISPERDAL / TOPAMAX Bipolar Positioning	Develop joint bipolar positioning for RIS/TPX	Psychs	Q3/Q4

**RISPERDAL®
MARKET RESEARCH
APPENDIX 4**

Market Research:

- Explore untapped market opportunities and expand effectively in additional geriatric markets
- Expand reach/Educate diverse audiences
- Strengthen positioning vs. competition/grow leadership dominance in elderly psychoses

2001 Market Research Plan:

Objective	Rationale	Target	Timing (start/finish)
Explore Untapped Market Opportunities And Expand Effectively In Additional Geriatric Markets			
Secondary Data Analysis: Elderly Psychosis Diagnosis and Treatment	Quantify elderly psychosis opportunity	Psy, GerPsy, PCP, Neuro	Q1/Q2
RISPERDAL Elderly Psychosis Promotional Message Development and Assessment	Test and refine our geriatric message for target audience	Psy, GerPsy, PCP, Neuro	Q3/Q4
Expand Reach/Educate Diverse Audiences			
PCP Surrogate Project	Utilize surrogate markers to identify PCPs with large geriatric populations. Evaluate APS utilization and trends among PCP surrogates	PCP	Q1
Geriatric Psychiatrist Focus Groups	Assess physicians' -- Geriatric Psychiatrists' and Psychiatrists with large elderly populations -- drug utilization, satisfaction, and unmet needs in managing elderly psychoses with existing APS agents	Psy, GerPsy	Q1
Nurse Practitioner (NP) Focus Groups	Assess Nurse Practitioner knowledge, attitudes, and practices in managing elderly psychosis	NP	Q2
XPonent Data Analysis: High Decile Prozac PCP Writers	Evaluate APS utilization among PCP high decile Prozac writers. Identify physicians and product usage profile.	PCP	Q2
Neurology Psychosis Analyses	Support RISPERDAL in Neurology initiatives	Neuro	ONGOING
Strengthen Positioning Vs. Competition/Grow Leadership Dominance			
RISPERDAL Elderly Psychoses Perceptual Map	Annual Awareness, Trial, and Usage Tracking and Positioning Study	Psy, GerPsy, PCP, Neuro	Q1/Q2
Intertrak Competitive Message Recall Study	Assess key competitors' (Zyprexa and Seroquel) sales promotion messages	Psy, PCP	Q2
Ziprasidone Geriatric Usage Study	Qualitatively assess ziprasidone potential penetration and uptake	Psy, PCP	Q2

	within the geriatric population		
RISPERDAL Elderly Psychosis Promotional Materials Development and Assessment	Support promotional material development (sales aid, leave-behinds, journal ads)	Psy, PCP	ONGOING
Ad Board Participant Surveys	Ensure survey instruments being used with Ad Board participants -- at the conclusion of the meetings -- provide value added information	Psy, PCP, Neuro	ONGOING
Quality Indicator Leverage Study	Marketing research to support development and measurement of programs around quality Indicators	Consulting Pharmacists, Nursing Home Nurses and Administrators	Q2
XPonent Data Analysis: FDAMA Impact	Post-launch tracking of LTC target universe to assess impact of the Katz study FDAMA distribution	Psy, PCP, Neuro	Q1