RISPERDAL®
2000 Business Plan Summary

OBJECTIVES:
RISPERDAL will be the antipsychotic treatment of choice for both psychotic and non-psychotic disorders. Average TRx share for 2000 will be 26.4% with sales of $1059.30 MM. The 2000 objectives by business segment are as follows:

Schizophrenia:
Accelerate growth to a schizophrenia market share of 20% and base sales of $583 MM.

Bipolar Disorder:
Differentiate RISPERDAL from other agents and establish a role in the treatment paradigm. Share will be 32% with sales of $175 MM.

Dementia:
Maximize and grow RISPERDAL's market leadership in geriatrics and long term care. Dementia share goal is 57% with sales of $302 MM.

FINANCIAL SUMMARY:

	Net Sales				Cost of Selling	% of Sales	PMEs	% of Sales
	$MM	% Chg	MM Units*	% Chg				
1998 Actual	695.4	18.1%	303.2	14.4%	12.9	1.9%	52.3	7.5%
1999 Aug Update	922.2	32.6%	389.8	28.6%	23.6	2.6%	66.5	7.2%
2000 Bus Plan	1059.3	14.9%	452.5	16.1%	25.0	2.4%	78.0	7.4%

*Includes tablets and oral solution

PME Breakdown:

	Total		Med Ed*		Samples/ Promotion		Journal Adv		PR		DTP/DTC		Agency	
	$MM	%Net Sales	$MM	%Net Sales	$MM	%Net Sales	$MM	%Net Sales	$MM	%Net Sales	$MM	%Net Sales	$MM	%Net Sales
1998 Actual	52.2	7.5%	32.9	4.7%	9.6	1.4%	4.0	.6%	3.4	.5%			2.3	.3%
1999 Aug Update	66.5	7.2%	43.5	4.7%	11.1	1.2%	3.9	.4%	5.6	.6%			2.4	.3%
2000 Bus Pln	78.0	7.4%	51.5	4.9%	14.3	1.3%	3.4	.3%	2.1	.2%	1.1	.1%	2.0	.2%

*Includes public relations, grants, sales support, and medical education programs

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KEY BRAND FACTS:

	1998	1999 YTD (9/99)	2000
Market NRx	11,735	9,625	12,935
Market TRx	22,928	18,504	25,855
NRx Share (%)	25.0%	27.5%	30.0%
TRx Share (%)	23.7%	26.1%	27.6%
Dollar Share (%)	31.9%	32.1%	31.2%
Share of Business by Indication/Specialty (NRx%)			
Schizophrenia	18%	18%	20%
Bipolar Disorder	27%	25%	32%
Dementia	45%	50%	52%
Share of Business by Indication/Specialty ($%)			
Schizophrenia	37.1%	23.2%	21.3%
Bipolar Disorder	45.1%	33.1%	32.2%
Dementia	48.1%	55.3%	57.6%
# Sales Calls	378,000	363,000	707,500
Share of Detailing (%)	36.9%	35.8%	34.5%
Share of Samples (%)	39.6%	33.4%	29.5%
Share of Journal Advertising (%)	30.8%	37.3%	35.4%
Share of DTC Advertising (%)	N/A	N/A	N/A

STRATEGIES - Schizophrenia:

1. Differentiate RISPERDAL from the competition
2. Expand reach on key customer base
3. Solidify and expand opinion leader support
4. Explore compliance opportunities
5. Maximize cost and reimbursement opportunities

STRATEGIES - Dementia:

1. Optimize efficacy and safety positioning
2. Rapidly drive market penetration
3. Expand reach with key customers
4. Develop advocacy and opinion leader support
5. Strengthen data generation and dissemination

STRATEGIES - Bipolar Disorder:

1. Differentiate RISPERDAL and disseminate benefits for appropriate patients
2. Strengthen opinion leader and advocacy support for RISPERDAL
3. Improve compliance and optimize patient management
4. Develop comprehensive clinical program (Medical Affairs Group)

RISPERDAL
2000 BUSINESS PLAN

I. RISPERDAL® (risperidone)

A. Strategic Vision

The vision of the RISPERDAL franchise is to reinforce the position of RISPERDAL as the antipsychotic of choice and to further establish Janssen as a leader in the CNS marketplace. Our focus in 2000 will be to enhance the leadership of RISPERDAL as the most effective atypical antipsychotic for first-line treatment of both psychotic and non–psychotic disorders. These disorders include schizophrenia, schizoaffective disorder, bipolar disorder, dementia and conduct disorders. RISPERDAL will also be building a foundation to launch future CNS products such as VESTRA, REMINYL, TOPAMAX-Bipolar and other future CNS compounds.

B. Market Overview/Situation Analysis

The antipsychotic market is valued at approximately $2.9 billion ($3.4 billion in RISPERDAL dollars), representing a dollar increase of over 23% from last year. It is projected that this increase in dollar volume will continue as the market rapidly converts from conventional antipsychotics (declining at about 10 share points per year) to more expensive atypical antipsychotics.

RISPERDAL has remained the #1 most prescribed antipsychotic in the United States for over 3 years. The current NRx share of 28.8% (Oct 99) represents an all time high.

In 2000, schizophrenia will remain a critical area of focus for RISPERDAL. Schizophrenia is the foundation for antipsychotic use and represents the greatest dollar potential (~$1.3 billion in RISPERDAL dollars). RISPERDAL currently has 18.0% share (MAT Sept 99) of the schizophrenia market, compared to 25.1% for Zyprexa. In 2000, our objective will be to accelerate RISPERDAL share growth, and ultimately retake the lead in this critical market.

The geriatric market represents RISPERDAL's second wave of growth. The incidence of dementia in the U.S. is about 3 MM people and demographic trends suggest the aging population will continue to drive market growth well into the next century. With one-half of all nursing home residents suffering from dementia (650 K), the long-term care (LTC) segment is a significant opportunity for RISPERDAL. In addition, many patients still live at home so prescriptions are being generated in the retail market as well. RISPERDAL LTC NRx is growing at a rate of 26% versus last year. In addition, YTD LTC segment sales exceed $120 MM, an increase of 11.5% over 1997. This solid sales growth has been facilitated by the introduction of 0.25mg and 0.5mg tablets, which are parity-priced with 1mg tablets. The parity pricing has helped to maintain sales despite a declining average daily dose. In fact, RISPERDAL continues to be the number one prescribed antipsychotic in LTC in terms of both market share and dollars. Increasing competition from Zyprexa and Seroquel is making this a much more competitive segment than in the past.

Bipolar disorder represents about one-fifth of the prescriptions for RISPERDAL, with a market potential estimated at nearly $600 MM. RISPERDAL has experienced significant growth in this market with a 25.2% share (MAT Sept 99), down from 26.8% in December 1998. Zyprexa has a current market share of 34.7%. Lilly's recent FDA "approvable letter" for Zyprexa bipolar labeling appears to have overcome an earlier setback in September 1998. A critical success factor for RISPERDAL will be effective positioning of the efficacy of RISPERDAL as adjunctive therapy without the significant weight gain liability of Zyprexa.

The continued publication of data supporting the efficacy and safety of RISPERDAL will drive the use of this product in a variety of psychotic conditions. Specifically, future developing markets for RISPERDAL include stuttering, conduct disorders in children and adolescents, post traumatic stress disorder and dual diagnosis.

In 2000, three major market forces will affect the overall antipsychotic marketplace:

- Increasing competitive intensity among existing atypical antipsychotics.
- Continued demand for new data and additional formulations of atypical antipsychotics.
- Changing reimbursement environment.

Competitive Intensity in Differentiating Atypical Compounds

The competitive environment of the atypical antipsychotic marketplace has intensified with a corresponding increase in the total dollar value of the market (an increase of 23% over last year). All pharmaceutical companies invested in the atypical antipsychotic marketplace have increased promotional intensity substantially. Most noteworthy have been Eli Lilly's expansion of LTC and bipolar-focused sales forces, AstraZeneca's increase by 100 LTC representatives, and significant spend by Pfizer in medical education programs and opinion leader focus in preparation for Pfizer's Zeldox. RISPERDAL must position itself as the antipsychotic with superior efficacy in order to differentiate from the other atypicals in 2000.

Continued Demand for New Data and Additional Formulations of Atypical Antipsychotics

Because of the importance of Zyprexa to the growth of Eli Lilly, a significant amount of resources—both human and financial—are devoted to their clinical development program. In addition to an extensive schizophrenia clinical program, Lilly has an advanced program for bipolar disorder which has resulted in an 'approvable letter' from the FDA. Lilly is also pursuing indications for dementia and Parkinson's dementia. In addition, new formulations including Zydis (a QuickSolv-like formulation), a patch, and a long-acting (depot) injection are also being aggressively developed. It is anticipated that Pfizer will re-file an NDA for ziprasidone in 1Q'00 with oral tablets, an IM formulation, and a claim for relapse prevention. Other schizophrenia products in development include aripiprazole (an Otsuka compound co-licensed with Bristol Myers Squibb - NDA late 2001) and Zomaril (Novartis - NDA mid-2001). RISPERDAL is significantly behind Zyprexa in terms of published clinical data as well as clinical research programs. Clearly, a major challenge for the CNS Franchise will be in providing resources to adequately support the development of new clinical data and formulations for RISPERDAL.

Changing Reimbursement Environment

The superior efficacy and safety profile of the atypicals has increased the NRx volume growth, and has dramatically increased the total dollar volume within the antipsychotic class. Atypical antipsychotics represent nearly two-thirds of NRx volume and over 90% of the existing dollars.

With the rapid shift towards the more expensive agents, it is anticipated that payors will continue to focus more attention on the use of atypical antipsychotics. Such changes will offer challenges and provide opportunities for RISPERDAL. In addition, there is a potential for change in the Medicaid reimbursement system. In 1998, the Prospective Payment System (PPS) was introduced in the Medicare nursing home population. PPS transfers the financial risk from Medicare to nursing home providers. Depending on the success of Medicare PPS, Medicaid may implement it's own version of capitated payment. With over 80% of RISPERDAL sales distributed via the public sector, this could have a significant impact on our business. Thus, the need to quickly expand and solidify RISPERDAL use becomes even more important.

C. Life Cycle Analysis – Schizophrenia/Geriatrics/Bipolar/Conduct Disorder

The atypical antipsychotic market is becoming increasingly competitive. The need to differentiate RISPERDAL from the competition with clinical data, new indications and additional formulations is critical. The primary focus will be to leverage our competitive advantage in schizophrenia, followed by expanding use in geriatric psychosis, bipolar disease, and conduct disorders. The potential of these markets is noted below:

Disease	Yearly Patient Population	$ Potential
Schizophrenia	2,500,000	$1.3 B
Bipolar Disorder	3,500,000	$640 MM
Dementia	2,900,000	$500 MM
Conduct Disorders	6,800,000	$300 MM

Schizophrenia:
The reanalysis of the RIS-112 data (RISPERDAL vs. Zyprexa) provides us with a strong opportunity to differentiate RISPERDAL from Zyprexa in the Schizophrenia market. In order to maximize these data, Medical Affairs will be analyzing the data to support several poster presentations and at least two manuscripts. RIS-79 (relapse prevention), is another important data set with regard to the schizophrenia market. Long term data is essential in this market. While the initial results of RIS-79 were released in 1999, several additional analyses are planned for 2000, as it is a robust data set. In addition, RIS-79 will be the key study to go for a long-term maintenance sNDA and potentially a superiority claim over Haldol for positive symptoms.

Dementia:
In order to maximize our competitive position and support our growth in dementia, a label change is critical. It is essential to co-operate with the FDA and opinion leaders in preparation for the Advisory Committee meeting scheduled for spring 2000.

With the increasing number of atypical antipsychotics on the market, the need to differentiate RISPERDAL from the competition on both efficacy and safety will be critical. The focus will be on expanding the data and supply of published literature on RISPERDAL in dementia patients with Alzheimer's Disease suffering from psychotic symptoms and behavioral problems. We have a large database with RIS-USA-63/RIS-USA-70 and RIS-INT-24/26, which could provide a wealth of data for years to come if analyzed effectively. It will also be important for us to

conduct head-to-head studies vs Zyprexa to combat the results of the Lilly sponsored RISPERDAL vs Zyprexa trial in dementia.

As we develop new formulations for RISPERDAL with depot we will need to ensure that appropriate low dose formulations for dementia patients are developed at the same time as doses for schizophrenic patients.

In order to maximize our CNS portfolio in geriatrics it will be critical to conduct studies with RISPERDAL and REMINYL regarding safety interactions and enhanced efficacy for both memory enhancement and behavioral control.

Bipolar:
The bipolar program includes RIS-102 and INT-46, both of which are critical for 2000 in order for us to remain competitive within the bipolar market. Both studies are acute mania, add-on studies and will form the basis for a bipolar sNDA to be submitted in June 2000. Acute mania monotherapy studies are expected to start 2Q'00.

Conduct Disorders:
RIS-USA-93 and the long-term extension RIS-USA-97 will provide us with data on the safety and efficacy of RISPERDAL in children with conduct disorders. These data will help us extend RISPERDAL use within the pediatric market and will potentially extend our patient with an additional 6 months.

The consistent practice of performing additional analysis on existing data sets is critical to maximizing the data, and therefore our publication exposure in the marketplace. However, with increasing competition, the need for new clinical data supporting the use of RISPERDAL in each strategic areas is also essential.

The long-term development plan for RISPERDAL is prioritized according to market potential. Our number one priority is the development of a RISPERDAL depot formulation. Several other new formulations, indications and line extensions are planned for launch within the next 1-5 years. A summary timeline of the new developments for RISPERDAL are summarized below:

	2000	2001	2002	2003	2004
Brand Introductions		QuickSolv Approval POC Approval	Depot (2-wk formulation)	Bipolar Monotherapy	Depot (4-wk formulation)
Label Changes New Indications New Data	Dementia Labeling Stuttering Data Dual Diagnosis Data Glucose Metabolism Data Long-term Conduct Disorder	Acute Mania Bipolar (adjunctive therapy Labeling) Maintenance Label	Conduct Disorders		Palmitate

	Data				
Key Publications	Comparative Data (RIS-112) Relapse Prevention (RIS-079) Bipolar – Acute (RIS-102/46) Conduct Disorder (RIS-93/RIS-97)	First-Break Data			

D. RISPERDAL- Schizophrenia 1999 Accomplishments and Lessons Learned

Accomplishments

- Overall NRx market share reached an all-time high seven out of eight months in 1999
- RISPERDAL sustained double-digit sales growth for the fifth consecutive year
- Zyprexa posted its first NRx share decline since launch
- The Janssen booth at the 1999 APA was rated Number One by attendees
- The CNS Summit has become a highly regarded meeting among opinion leaders

Lessons Learned

We need to focus on a specific promotional schizophrenia message

Since the launch of RISPERDAL in 1994, the base promotional message has focused on efficacy in "psychosis." This broadly defined message has been effective in diversifying the range of diagnoses for which RISPERDAL has been prescribed, but has also diluted the core message for schizophrenia. Zyprexa surpassed RISPERDAL in schizophrenia market share in May of 1998, and while RISPERDAL has remained flat at an NRx share of 18.2%, Zyprexa has grown its NRx share in schizophrenia to a new all-time high of 25.1%. In 2000, our promotional and medical education activities will need to focus on driving a strong evidence-based message for the efficacy of RISPERDAL in the treatment of schizophrenia.

Seroquel (quetiapine) cannot be ignored

In spite of the fact that the psychiatric community continues to question the efficacy of Seroquel, it currently has a NRx share of 7.1%. In addition, Seroquel has shown consistent growth that has actually outpaced growth rates for both RISPERDAL and Zyprexa in the last year. Zyprexa is and will remain the main competitor for RISPERDAL, but it will be important to make sure that we maximize every opportunity to blunt the continued growth of Seroquel.

Weight gain is a defensive issue for Zyprexa, and an offensive issue for ziprasidone

Lilly is now defensively addressing the issue of weight gain in their sales materials, but Pfizer is quickly trying to pre-position ziprasidone as weight neutral. There is also further evidence that Zyprexa may be associated with causing Type II diabetes in some patients. We will need to explore this further, as this would have significant impact on the medical community. Until we know further, we need to continue to firmly position RISPERDAL as the most effective first-line atypical, while differentiating on weight gain as a secondary message.

The antipsychotic marketplace is still price inelastic

Despite the fact that Zyprexa is typically priced 40% higher per prescription than RISPERDAL, the market still remains slow to react to this difference in terms of formulary positioning.

Publication opportunities have not been fully leveraged

Janssen is significantly behind Eli Lilly in terms of studies and related publication volume. There have been few new studies since launch in 1994, and the data sets we do have are not fully leveraged to produce multiple publications.

E. SWOT Analysis - Schizophrenia

The SWOT analysis is the basis for RISPERDAL-Base promotional activity in 1999:

Strengths	Weaknesses
Superiority in positive and negative symptoms over Haldol Relapse prevention data (RIS-79) New data Vs Zyprexa (RIS-112) Rapid onset of action Low weight gain QD dosing Low TD Low anticholinergic effects Low sedation	Publication Volume Dose-Dependent EPS Perceived TD liability (EPS) Prolactin elevation Perception of more complex dosing Breadth/number of speakers
Opportunities	**Threats**
Acute care setting Psychiatric Residents Low cost/changing reimbursement environment Opinion leaders	WLF ruling Zeldox (ziprasidone launch) tablets and IM formulations Zyprexa "Zydis" (quick-solv) and IM formulations Growth trend of Seroquel Zyprexa bipolar approval

F. Key Issues - Schizophrenia

Increasing Competitive Intensity

1) *Decreasing share of voice*
   In the year 2000, there will be four atypicals on the market which are actively promoted, with a fifth due to be approved by year-end (ziprasidone). While this increases the "noise level" for the atypicals overall, it also creates more fierce competition. There will be more representatives promoting each drug, either from corporate mergers (Astra-Zeneca), sales force expansions (Janssen and Lilly), or a new drug launch (Pfizer). From a promotional standpoint, representatives then face more competition for physician time. At a different level, there will be increased competition for opinion leader relationships. Medical education will also be more challenging, with five companies actively pursuing the antipsychotic market, and therefore competing for physician time at major meeting symposia, and representative delivered programs. To be successful in 2000, we will need to ensure that promotional messages are solid in content, and that they are consistent from rep-to-rep and program-to-program. We will also need to continue to strengthen our existing relationships with key opinion leaders, and strive to further widen our circle of key contacts.
2) *Existing perception gap*
   To regain market share in the treatment of schizophrenia, we must address current perceptual gaps relating to the product profile of RISPERDAL. Market research has shown that prescribers feel that Zyprexa is superior to RISPERDAL in the treatment of negative symptoms, and that it has a superior EPS profile. In contrast, however, the large evidence

of clinical data demonstrates both drugs to be equal. In addition, weight gain and diabetes were not listed as part of the top 10 attributes of importance to physicians, although both were rated strongly in favor of RISPERDAL. Our current promotional message focuses on efficacy, low weight gain and appropriate dosing. We will need to continue to drive this core message, and work to close the existing perceptual gaps versus Zyprexa. We also need to raise the overall importance of weight gain and diabetes with key prescribers.

3) *Sub-optimal physician targeting*
In the interest of pursuing high volume prescribers, Janssen has not devoted a great deal of selling time to psychiatric residency programs, acute setting psychiatrists, or psychiatric nurses. We now have a dedicated sales force in institutional settings that will allow us more time with these important customers. Promoting RISPERDAL to all of these key customers (in addition to high volume physicians) will allow our representatives cover the continuum of patient care.

Poor Compliance
Similar to other atypicals, market research has shown that for every 100 patients, who begin RISPERDAL treatment, only 15 will remain on RISPERDAL one year later. The reason for this alarmingly high rate is complex, stemming partly from the diagnosis itself and compounded by a very fragmented mental healthcare system. Countless programs have been put in place from various organizations, all aiming to correct the problem. While this is a key issue for RISPERDAL, any tactics aimed at addressing poor compliance must be carefully considered as to their projected impact.

Low Cost and Challenging Reimbursement Environment
In spite of the fact that RISPERDAL is 40% less expensive per patient than Zyprexa, and approximately 30% less expensive than Seroquel, we have not yet seen payors move toward preferring one atypical over another on formularies to any significant degree. We must first differentiate the efficacy and safety product profile of RISPERDAL with payors. This message can then be combined with a strong cost-effective message to move toward gaining preferred formulary status.

Secondarily, the JanssenCares patient assistance program has experienced some blatant misuse in certain states. Some counties have decided to implement this patient assistance program as a chief source of funding for RISPERDAL medication, instead of paying for the drug based upon county budgets. We will need to evaluate whether this "misuse" is part of the cost of doing business, or if we should redesign the program at the risk of alienating key customers.

Timing and Scale of Clinical Development Plan
The role of our clinical data development is crucial for maximizing RISPERDAL's potential in Bipolar Disorder. Clinical data is essential to support our strategy of differentiation. Positive data to show RISPERDAL's superior properties of rapid onset of action and low weight gain in relation to Zyprexa, Depakote, and Lithium will be important for success in 2000.

Aggressive Competition
Zyprexa is RISPERDAL's main competitor in Bipolar Disorder. Lilly has recently received a FDA approvable letter for bipolar mania for Zyprexa. This letter was issued in October 1999 and formal approval should occur during the last quarter of 1999. Lilly will be able to promote Zyprexa for Bipolar Disorder in 2000, which makes the timing of our clinical development plan even more crucial, as it will determine our capacity to promote RISPERDAL in Bipolar Disorder.

G. 2000 Business Objectives - Schizophrenia

Quantitative:
Base business sales: $583 MM
December Schizophrenia share: 20.0%

Qualitative:
To accelerate share growth in schizophrenia, with the ultimate goal of recapturing the lead position in the treatment of schizophrenia. With the introduction of the RISPERDAL relapse prevention study in schizophrenia, as well as the competitive trial versus Zyprexa, we will have the evidence we need to reclaim the number one position.

H. Key Strategies with New Tactics for 2000 - Schizophrenia

Strategy #1: **Differentiate RISPERDAL from the competition**
- RISPERDAL.com
- Influence Network Marketing dinner meetings
- Field-Based Psychiatry Advisory Forums
- Ziprasidone Blocking Kit
- Sales Training Motivational Tapes

Strategy #2: **Expand Reach on Key Customer Base**
- Janssen Resident of the Year Award
- Residency to Practice Management Seminars
- Virtual Hallucinations Education Endeavor
- ER education pack
- Psychiatric Nurse Home Office Advisory Forum
- APNA Newsletter

Strategy #3: **Solidify and Expand Opinion Leader Support**
- Speaker Intranet/Slide Updates

Strategy #4: **Explore Compliance Opportunities**
- Compeer Program
- Discharge Planning Kit
- DTP Pharmacy Intervention

Strategy #5: **Maximize Cost and Reimbursement Opportunities**
- Leveraging Economic/Clinical Competitive Advantages
- Public Sector Forums

I. Sales Force Requirements - Schizophrenia

Call activity and capacity are as follows:

Sales Force	Annual Call Capacity	RIS 1st	RIS 2nd	VESTRA 1st	VESTRA 2nd
S (165)	254,100	254,100			192,693
I (52)	114,400	114,400			71,500
T (121)	199,650	33,275	124,780	166,375	
Total	568,150	401,775	124,780	166,375	264,193
Scios (94)	50,000	50,000			

Message:
The sales force message for 2000 will be:

- **Differentiate on efficacy in schizophrenia**
  - significantly superior: positive and negative symptoms
  - improvement as soon as week one
  - sustained improvement
- **Discuss low weight gain**
  - 5.7 lbs. after one year
  - consider the short term/long term effect of weight gain
- **Stress appropriate dosing**
  - starting dose 2 mg QD
  - target 4-6 mg in schizophrenia

Specialty "S" and Target "T" reps will co-promote RISPERDAL in community office-based settings. Institutional reps will be asked to spend time with their key customers in the ER, to promote the use of RISPERDAL in the acutely agitated patients. They will also be asked to spend more selling time with psychiatric residents so that these important customers of the future can begin to build positive experience with the use of RISPERDAL. It will also be important for institutional reps to interact with and promote the benefits of RISPERDAL to psychiatric nurses, because these customers are highly influential in generating medication switches.

Programs:
All medical education program topics will be designed to discuss the same three key communication points.

- Teletopics
- Distance Learning Network Satellite Programs
- Peer to Peer Meetings
- Speaker Programs
- Symposia
- Audiotapes

See attachment 5a for complete listing

J. Business Imperatives - Schizophrenia

Publication of Relapse Prevention and RISPERDAL vs Zyprexa Studies
These two studies provide solid evidence of the superior efficacy of RISPERDAL in the treatment of schizophrenia. The data strongly reinforce our sales message in schizophrenia and publication will significantly aid us in regaining lost market share in schizophrenia. Once published, we will submit these studies to internal review, with the ultimate goal of having the sales force distribute them under Washington Legal Foundation guidelines.

Lessen the Perceptual Gap Between RISPERDAL and Zyprexa in Negative Symptoms and EPS; Elevate Importance of Weight Gain and Diabetes
We will conduct another perceptual map survey with 300 key customers in 1Q'00. We will minimize the gap between RISPERDAL and Zyprexa on these two attributes, utilizing the 1999 survey for baseline results. We will also shift the overall importance of weight gain into the top ten categories, and raise awareness of diabetes risk with competitors.

Implement Ziprasidone Blocking Strategy with Sales Force Prior to Launch
We will provide the sales force with a thorough review of Pfizer as a company, their strategies for ziprasidone, and an overview of the clinical data with thorough commentary and interpretation. We will also provide the sales force with specific lists of physicians who are likely to prescribe ziprasidone at launch. It will be imperative that 100% of the sales force is fully trained and understands how to position RISPERDAL versus ziprasidone by August of 2000.

Establish Productive Working Relationships within Public Sector Markets
Timely identification and management of RISPERDAL business opportunities, threats and vulnerabilities will be essential. Reimbursement managers will establish productive working relationships with payers in Medicaid, State Mental Health, CMHCs, Counties, VAs, Department of Corrections and Behavioral Health Organizations leveraging clinical and pharmacoeconomic advantages.

Manage Public Sector Market Trends such as Budget Limitations (Diminishing Elasticity, Zyprexa Expenditures), Medicaid Managed Care and State DUR Threats
We will design and implement CME public sector forums, maximize our Performance Guarantee Program, and DUE forms with targeted top level decision makers and institutions. Each reimbursement manager will be responsible for multiple programs and selected participation in advisory boards (Corrections, VA, Medicaid and State Mental Health) with the overall goal of maximizing RISPERDAL's formulary position and business growth.

D. RISPERDAL- Geriatrics 1999 Accomplishments and Lessons Learned

Accomplishments

- Increased RISPERDAL market share in dementia from 43.0% in Sept. 1998 to 51.1% in Sept. 1999 for a total increase of over 8 share points.
- Launch of the .25 mg and .5 mg tablets.
- Doubled use of teletopics to over 500.
- Increased attendance at nurse programs by 30%.
- Enhanced relationships with key associations including AMDA, ASCP, and AAGP.
- Better understanding of dosing by physicians. All called on physicians are primarily using low doses in the elderly in the .25 - 2 mg range.

Lessons Learned

- In the geriatric market it is vitally important to balance our safety and efficacy messages. Market research has indicated efficacy is the most important attribute a physician looks for in gaining control of agitated and/or aggressive behaviors. Our physicians believe this is a clear Risperdal strength. While no single safety parameter is more important than efficacy, it is also clear safety is extremely important, i.e., EPS, TD, sedation, anticholinergic profile, etc. We have the most robust data available and we intend to continue to leverage this data stressing, in parallel, our unsurpassed efficacy and safety messages.
- Without proper education PPS and OBRA regulations could negatively impact antipsychotic prescriptions in the nursing home. PPS has more fully impacted nursing homes, as the 3 year staged national rollout is nearly complete. This has caused some nursing homes to increase pressure on physicians to prescribe less expensive drugs such as conventionals. Proper education on overall health care cost reductions and improved patient care with RISPERDAL is important in this environment.
- Nurses are key influencers over switching and diagnoses. Physicians are very open to taking advice from director's of nursing and other nurses since they are with the patients, observing symptoms and side effects for such a great amount of time.
- Important to stress proper dosing or physicians will switch because of EPS. EPS with RISPERDAL is dose dependent and when used at 2 mg or greater in geriatric patients there is far greater risk of EPS. Currently, the dosing in our package insert does not indicate the truly appropriate range for patients.
- Target audiences are still interested in treating behavioral symptoms more than "psychotic" symptoms. Physicians will treat psychotic symptoms such as paranoia, delusions, and hallucinations when they involve aggression or agitation that becomes problematic for the patient and staff.
- The LTC market is very responsive to promotion, however it is becoming increasingly more competitive as Eli Lilly and AstraZeneca both have launched sales forces in the LTC market.

E. SWOT Analysis - Geriatrics

Strengths	Weaknesses
Efficacy/safety data (RIS-63 & RIS-70) Market leadership Performance based contracts J&J LTCM/ElderCare team Availability of dosing options	EPS at ≥ 2mg/day Physician/customer targeting due to data Delay in label change for RISPERDAL No switching or 'head-to-head' data Dosing confusion OBRA Orthostatic hypotension
Opportunities	**Threats**
RIS-OLZ Dementia Trial Additional 'pull-through' programs REMINYL synergy OL/association relationships WLF AUS-5 Study	Dementia label for Zyprexa Dementia label denied for RISPERDAL Competitive sales force expansions Zeldox/Aricept/Zoloft synergy Seroquel geriatric focus AChE, AC & ADP use PPS Lilly comparative trial

F. Key Issues - Geriatrics

Increasing Competitive Intensity

As the competition grows among the atypical antipsychotics and our competitors add 'ElderCare-like' sales forces it becomes more important for us to maintain our share of voice. Our competitors are also publishing off-label data prolifically and these may dilute the impact of our few small Phase IV studies in geriatric patients. In addition, both Lilly and Zeneca have increased their share of voice at national conventions and with national and regional CME education.

Increased Focus on Opinion Leaders

Competitive intensity is increasing for share of voice with the opinion leaders as well. In geriatrics there is a small number of really top tier opinion leaders. These individuals are all being strongly pursued by both Eli Lilly and AstraZeneca. We will need to ensure coverage of these opinion leaders in order to build and maintain the relationships we have already established. We should also leverage our REMINYL position when maximizing our relationships with the opinion leaders.

Perceptual Gap

A perceptual gap exists between RISPERDAL's clinical data in geriatrics and the perception physicians hold who treat geriatric patients. RISPERDAL is perceived as having a worse safety profile that the drug actually has, often because physicians are using inappropriately high doses. In addition, most physicians do not recognize that RISPERDAL is the only drug with proven data on efficacy in geriatric patients.

Sub-optimal Customer Targeting

Sub-optimal customer targeting exists as a result of lack of decile data on physicians who treat geriatric patients in nursing homes and hospitals. A broad number of health care professionals, with a varied understanding of antipsychotics, influence patient treatment and switching. It takes a great deal of time and education to ensure that all of the members of the treatment team understand the impact of using RISPERDAL in their geriatric patients or any one "weak link" in the treatment team can negatively impact the business. The primary care audience needs additional education and coverage. This will be substantially increased in 2000, with over half of the antipsychotic decile 4-9 primary care physicians called on. Our coverage will increase to almost 75% after the sales force expansion.

Reimbursement "Window of Opportunity"

We have a reimbursement window of opportunity that is beginning to close as the Prospective Payment System (PPS) more fully impacts nursing homes. By the end of 2000 PPS should be fully implemented nationwide. PPS encourages nursing homes to manage total drug costs downward and thus encourages the use of conventionals vs. atypicals. It will be important for RISPERDAL to capture as much share as possible in order to prevent possible erosion of market share and to insure there is a better understanding of the overall treatment cost savings with RISPERDAL. In addition, the cost gap between RISPERDAL and other atypicals is narrowing in patients diagnosed with dementia. Zyprexa's dosing size continues to decline which makes it only slightly more expensive than RISPERDAL and the newest atypical, Seroquel appears to be priced at a slight discount to RISPERDAL although the data is fairly thin to determine the average dose and cost in dementia patients.

FDA Changing Position

The FDA has recently developed some hesitation on granting specific indications on the use of antipsychotics in Alzheimer's patients with psychotic symptoms. Previously, the FDA had indicated it was very likely RISPERDAL would be granted this label change. The FDA has declined approval for Zyprexa and has announced it will hold an advisory committee meeting in the spring of 2000 to discuss all the issues before granting any approvals.

G. 2000 Business Goals & Objectives - Geriatrics

Quantitative:

Geriatric Sales: $302 MM
December Share: 57%

Qualitative:

Maximize and grow RISPERDAL's market leadership in geriatrics and LTC

H. Key Strategies and Tactics - Geriatrics

Strategy #1: **Optimize safety and efficacy positioning**

- CNS Advisory Forums
- Dementia labeling change preparation (FDA advisory committee meeting) and Dementia launch promotion and PR preparation
- Dementia IPT CD-ROM
- CME speaker's bureau

Strategy #2: **Rapidly drive market penetration**

- Nursing home team education
- PPS video and symposia
- TeleTopics

Strategy #3: **Expand reach to key customers**

- PCP CME teleconferences
- Nurse collegia
- Patient/caregiver educational brochures

Strategy #4: **Develop advocacy and opinion leader support**

- PCP Advisory boards co-sponsored by RISPERDAL and REMINYL brand teams
- Advisory boards with geriatric psych residency training directors
- Advisory boards with Directors of Assisted Living Facilities
- Advisory boards with key Nurse Practitioners
- Educational program development with AAGP, AMDA, AGS, NADONA, ASCP

Strategy #5: **Strengthen data generation and dissemination**

- Analyze RIS-63 and RIS-70 data
- Increase number of small, investigator initiated studies in geriatric patients
- Increase body of peer reviewed published data for use under WLF

I. Sales Force Requirements - Geriatrics

Calls – ElderCare, with the expansion to 136 representatives by March, should provide a total of 65,500 calls for RISPERDAL - geriatrics for 2000.

Message –
- RISPERDAL has proven efficacy in treating geriatric patients
- RISPERDAL has an excellent safety and tolerability profile in geriatric patients
- RISPERDAL is easy to dose with our flexibility of formulations and easy titration

Programs -

ElderCare

- Speaker's bureau
- TeleTopics
- PCP teleconferences
- Videos
- Case workbooks
- Nurse Collegia
- Advisory Forums
- SLU Preceptorship
- Giveaways
- Backgrounder
- Patient/caregiver brochure
- Patient pill box
- New campaign materials
- Safety fact sheets
- Dementia launch
- Advisory Forums
- SLU Preceptorship
- IPT CD-ROM

LTC Business Management Team

It is increasingly important to work closely with this team and we will continue to support their efforts with their primary customers the pharmacy providers (Omnicare, PharMerica, NCS and NeighborCare). We have set aside specific programs and budgets for this team.

- Speaker's bureau
- TeleTopics
- Videos
- GNC education program
- Advisory Forums
- Giveaways
- Backgrounder
- Safety fact sheets
- Dementia launch
- Advisory Forums
- SLU Preceptorship

J. Business Imperatives - Geriatrics

Expand Reach with PCPs

The ElderCare initial expansion will increase the size of the sales force from 86 to 136 representatives. This will enable the sales force to increase reach and frequency of antipsychotic decile 4-9 primary care physicians from 2,600 in January to 4,500 by March. It is imperative that we reach all 8,000 decile 4-9 physicians with Risperdal promotional items at least twice in 2000. This will be done through direct mail and teleconferences where we do not have coverage of physicians. In addition, we will achieve 2 calls per quarter on at least 90% of the 4,500 primary care physicians we are calling on with ElderCare.

Implement a Successful Plan for the FDA Advisory Committee

A white paper will be developed which will effectively summarize RISPERDAL's efficacy and safety data in geriatrics. Data will be compiled from key Janssen studies such as RIS-USA-63, RIS-USA-70, RIS-INT-24 and RIS-INT-26. This will be disseminated prior to the FDA Advisory Committee meeting on the use of antipsychotics in the elderly. We will also leverage the behavioral data contained in our REMINYL Phase III trials.

In addition, a complete backgrounder on the FDA advisory committee members will be disseminated to internal Janssen personnel. The backgrounder will include publication histories, and other appropriate information and this will assist our regulatory group in negotiating a favorable outcome for RISPERDAL regarding label changes in geriatrics.

Generate/Disseminate Clinical Data

It will be critical to generate publications in 2000 through additional analysis of the large RIS-USA-63 and RIS-USA-70 databases. Preliminary analysis should be complete by Q3'00 and pursuit of publications, where applicable, should be sought by end of year.

We will also begin comparative studies with RISPERDAL vs. Zyprexa by end of Q2'00 to assess primarily anticholinergic side effects with other secondary measures in place. A RISPERDAL/REMINYL combination use study should be assessed by end of Q2'00 and if it is determined that it is in the best interest of both products the study should begin, at the latest, by the beginning of Q4'00. The RISP/REM study will likely primarily focus on pK and safety issues with efficacy a secondary measure.

Increase Focus on Opinion Leaders

Opinion leader development is an important strategy for us in 2000 and as such it will be very important for us to ensure both MSL and representative coverage of at least the top 30 opinion leaders in geriatrics. MSL capacity will be assessed to determine if they will be able to call on additional opinion leaders. The representatives will call on the top 100 opinion leaders in geriatrics at least 10 times.

D. 1999 Bipolar Accomplishments and Lessons Learned

Accomplishments

- Focused marketing effort to maximize synergies between RISPERDAL and TOPAMAX
- Organized brand team and developed strategic and tactical plans for 2000
- Initiated Bipolar opinion leader development in conjunction with TOPAMAX

Lessons Learned

RISPERDAL used as add on agent for antipsychotic effects in bipolar disorder
The norm in the treatment of bipolar disorder is to combine therapies. Market research shows that 73% of patients are treated by a combination of therapies. In this context RISPERDAL is not an exception and has been prescribed as an add-on therapy for its antipsychotic effects.

Need data in bipolar disorder to further differentiate RISPERDAL from Zyprexa
In order to differentiate RISPERDAL from Zyprexa, we need to generate clinical data in bipolar disorder and communicate positive results effectively to the psychiatric community. Market research indicates that physicians perceive RISPERDAL as stronger on "improving quality of life" and "reduced risk of weight gain". We must generate clinical data to show that. Positive data from clinical studies will be the foundation for growth in the bipolar segment.

Patients change therapy due to weight gain
The importance of the weight gain side effect is evident. Weight gain affects compliance. Market research shows that one third of the patient population changes therapy due to weight gain. In this way, weight gain is a major obstacle for compliance in the treatment of bipolar disorder. Market research indicates that at least 50% of prescribers associate the use of Zyprexa, Depakote, or Lithium with weight gain. While low weight gain is an important property for patients and prescribers, Zyprexa, Depakote, and Lithium are not associated with this attribute according to the physicians' perception.

Effectiveness and weight gain are 'differentiating' factors
Effectiveness, including rapid onset of action and low weight gain are key properties that may become important differentiating factors for RISPERDAL in bipolar disorder. The psychiatric community considers these attributes important as they improve compliance and patients' quality of life. As we generate and disseminate positive clinical data to support those attributes for RISPERDAL, we will have a strong competitive advantage in relation to Zyprexa, Depakote, and Lithium.

E. SWOT Analysis - Bipolar

The SWOT analysis is the basis for RISPERDAL Bipolar promotional activity in 2000:

Strengths	Weaknesses
Familiar APS profile Low weight gain Cost advantage vs. Zyprexa Faster onset of action vs. mood stabilizers "Improves quality of life" RIS-USA-112 Data (Anxiety/Depression)	Dose-dependent EPS risk Conventional agents perceived as faster acting in mania Perceived mania induction
Opportunities	**Threats**
RIS-USA-102 Unsatisfied Market & RIS-INT-46 Data Leverage Topiramate interest into RISPERDAL support BD depression & maintenance Improve compliance	Zyprexa BD mono-therapy label change: Acute indication (4Q'99), Depression (4Q'01), Maintenance (4Q'02), Zyprexa vs Depakote data Zeldox launch Seroquel fast growing market share

F. Key Issues - Bipolar

Large Dissatisfied Market
The diagnosis, and treatment and management of bipolar disorder is very complex. Market research indicates that the psychiatric community is not satisfied with the available choices for treatment of bipolar disorder. 98% of specialists want to make adjustment in treatment. This dissatisfied population of physicians and patients represents a major opportunity for RISPERDAL given its superior attributes of rapid onset of action and low weight gain.

Timing and Scale of Clinical Development Plan
The role of our clinical data development is crucial for maximizing RISPERDAL's potential in Bipolar Disorder. Positive data to show RISPERDAL's superior properties of effectiveness, rapid onset of action and low weight gain in relation to Zyprexa, Depakote, and Lithium will be important for successful differentiation.

Aggressive Competition
Lilly has recently received a FDA approvable letter for acute bipolar mania for Zyprexa. This letter was issued in October 1999 and formal approval is expected in December. Lilly will be able to promote Zyprexa for Bipolar Disorder in 2000, which makes the timing of our clinical development plan critical.

Weak Opinion Leader Support Base
A key factor for RISPERDAL's success in bipolar is opinion leader support. Few programs were developed to enhance RISPERDAL's opinion leader support in the past. Consequently, few opinion leaders supported the use of RISPERDAL bipolar disorder. Opinion leader support is essential for obtaining expert endorsement for use in bipolar disorder. These same expert

endorsement for use in bipolar disorder. These same experts also conduct seminars and dinner meetings, etc., at which they endorse RISPERDAL.

Poor Patient Compliance and Management
The poor patient compliance and management in bipolar represents a major opportunity for RISPERDAL. Many bipolar patients are non-compliant with their medications for a variety of reasons. Side effects from mood stabilizers, such as weight gain, tremor, hair loss causes 50% of patients to discontinue therapy at some time during treatment. In fact they average length of therapy is only 70 days, in a disease which daily therapy is recommended. Non-compliance increases the chance of an acute bipolar episode and also reduces the sales of drugs used to treat bipolar disorder. Improvement in patient compliance and management will enhance RISPERDAL usage and strength its position as the treatment of choice in bipolar disorder.

G. 2000 Business Goals & Objectives - Bipolar

Quantitative:
Bipolar business sales: $175 MM
December TRx: 32.0%

Qualitative:
Differentiate RISPERDAL from other agents in Bipolar Disorder capitalizing on RISPERDAL's effectiveness as add-on therapy, fast onset of action, and low weight gain.

H. Key Strategies and Major Tactics - Bipolar

Strategy #1: **Differentiate RISPERDAL & Disseminate Benefits for Appropriate Patients**

- RIS-102/46/112 Dissemination Program
- Regional CME Programs: 3 Tracks
- RISPERDAL Evolution
- Publication Program
- Bipolar Sales Training and Targeting Program

Stragegy #2: **Strengthen Opinion Leader and Advocacy Support**

- Millennium Leaders
- RISPERDAL BD Symposia
- CME Casexchange BD Meetings
- MSL Program
- Janssen Resident of the Year Award

Strategy #3: **Improve Compliance and Optimize Patient Management**

- NDMDA Ultra-Care & Patient Max Programs: Diagnostic Kit and Patient Treatment Guide
- NIMH Educational Program: "New Developments in the Diagnosis and Management of BD for Community Psychiatry"

I. Sales Force Requirements - Bipolar

Programs:
The sales force will be involved in three medical educational programs and one training program, as follows:

RIS-102/46/112 Dissemination Program
The sales force will disseminate a sealed reprint pack to physicians with the results of the RIS-102, 46, and 112 studies. We expect to have the sealed reprint packs by the end of the first cycle for RIS-112 and third and fourth quarters for RIS-102 and RIS-46.

CME Casexchange Programs
All sales representatives will be involved in this program. Each sales representative will invite 10 to 12 psychiatrists to each dinner. A logistics agency will be utilized to assist in the organization of this program. Janssen will sponsor a series of 320 CME accredited dinner meetings in 2000.

Regional CME Programs: 3 Tracks
These 60 one-day CME programs will be held in the top 25 markets across the country. Each meeting will have at least 50 community psychiatrists attending. Our sales force will be able to deliver invitations during the recruitment process. We recommend the attendance of sales representatives and district managers to each meeting.

Bipolar Sales Training Program
The sales representatives will be trained on bipolar disorder. We are planning presentations at the district meetings and sales training classes. Didactic materials will also be provided to sales representatives. Training videotape on bipolar disorder is expected to be completed by the end of the first quarter.

Targeting
Treatment of bipolar disorder, and consequently the use of drugs to treat the disease, is concentrated among minority of psychiatrist. Approximately 3500 physicians are responsible for half of the prescriptions for mood stabilizers. Similarly, 7000 psychiatrist are responsible for 80% of the total volume and 10,000 for 90% of volume. Cross-mating decile 8,9, 10 mood stabilizers and antipsychotics identify 3600 high volume target psychiatrists. Approximately 67% are currently called on by the Janssen sales organization. Targeted lists by territory will be available for use in 2000.

J. Business Imperatives - Bipolar

In order to achieve the presented business goals and objectives, the following deliverables are critical:

Use appropriate data to blunt Zyprexa launch
It is mandatory to utilize onset of action, effectiveness, and weight gain data currently available to blunt the Zyprexa launch. All data about RISPERDAL's superior attributes must be well disseminated to the psychiatric community.

- Regional CME programs completed – 20 per quarter 2Q'00 through 4Q'00
- 300 CME case exchange (dinner meeting) programs completed
- 4 posters, 2 journal articles, and 1 supplement in each quarter of 2000

Quality and timing of studies

The quality and timing of RIS-USA-102 and RIS-INT-46 studies are crucial in order to achieve the 2000 qualitative and quantitative objectives. Positive and timely data will help to differentiate RISPERDAL from Zyprexa.

- RIS-USA-102 Manuscript completed and submitted 1Q'00
- Accepted for publication and published 2Q'00
- Field force sealed reprint distributed 2Q'00
- RIS-INT-46 sealed reprint distributed 4Q'00

Strengthen Opinion Leader Support

It will mandatory to strengthen bipolar opinion leader support. Existing relationships should be reinforced and new relationships established. Support from Bipolar opinion leaders will be crucial to success in 2000.

Opinion Leader Support

- Develop individual relationship plans for top 100 opinion leaders and MSL call plan
- Conduct 1 regional advisory board per quarter and 2 national advisory boards in 2000
- Sponsor 1 national preceptor program per quarter in 2000
- Sponsor 5 visiting professors programs per quarter in 2000