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02. Mission Statement and Product Positioning

Summary of Accutane's mission and positioning within the market

Strategic mission

The strategic mission for the Accutane team is to:

Continue to grow the brand through increased appropriate use in well qualified and well counselled patients.

Protect the franchise long-term through product and market development activities which result in additional market exclusivity for Accutane.

Supporting Strategies

There are four key strategies which have become the core in marketing the Accutane brand. All other strategies flow from these strategies listed below:

- 1. Insure appropriate use of Accutane, with specific emphasis on females of childbearing potential.
- Drive untreated disease sufferers, especially young men with severe acne, to seek medical treatment of their acne.
- Facilitate and enhance an ongoing dialog between doctors and patients so that patients have a
 realistic expectation of their treatment and ultimately are satisfied that their acne has been
 effectively treated.
- Protect the brand franchise long term through timely revision to, and implementation of the lifecycle plan, and by responding swiftly and decisively to all threats to the Accutane brand.

Personal promotion, journal advertising, direct mail, Physician & Nurse Speaker Programs, publications on Accutane new formulation will be the key venues employed in reaching our target healthcare professionals.

Television (DRTV), Print and Internet will be used to reach consumers.

Pharmacy CE, Pharmacoeconomic studies data and other value-added programs will be used to facilitate conversion to Accutane new formulation in the Managed Care setting.

It is vital that Roche continue to expand the knowledge base around the treatment of acne and related conditions. Roche will also continue to define possible and potential Adverse Events. The integrated medical plan will focus on these issues through publication strategies, Roche sponsored trials, and investigator initiated studies.

The successful launch and market conversion from Accutane current formulation to Accutane new formulation (slated for March 2001) is absolutely essential and critical, not only to year 2001 product revenues, but to all future year revenue flows.

(Important Note: A separate, completely inclusive Accutane New Formulation Launch Plan, executed in both hard copy and as a BOG presentation is planned for mid-year.)

Product positioning statement

The Accutane product position is as follows:

Severe acne is a disease which may cause profound negative physical and social effects if not adequately treated.

Accutane is the only product capable of producing dramatic clearing and long-term remissions in patients with severe recalcitrant nodular acne.

(Important Note: This positioning statement will be modified to include additional key benefits pending the completion of Market Reseach activities on the new formulation.)

However, Accutane must be used with caution because it is a teratogen and may potentially cause serious Adverse Events.

Product Key Promise

Only Accutane has produced dramatic clearing of the most severe types of acne (SRNA) and maintained that clearing for the long term

(Important Note: This product key promise statement will be modified to include additional key benefits pending the completion of Market Reseach activities on the new formulation.)

A. Patient Dynamics

Demographics:

Accutane continues to be the only effective therapy for severe recalcitrant nodular acne. Since 1996, it has experienced annual true growth in excess of 10% per year. It continues to outpace all other major acne therapies.

A major part of this growth has been in the patient pool itself. There are no studies to indicate the actual incidence and prevalence of severe recalcitrant nodular acne in the United States. The latest available study on the general prevalence of acne was conducted by NHANES in 1974. According to estimates, approximately 2% of the population suffers from acne. Of this group, 22% have severe acne. As of the latest population count (March, 2000) this puts the count of severe acne sufferers at 1,208,000. This also represents an increase of 5.5% in the severe acne sufferers over 1995. According to NDC Health, at year end 1999 there were a total of 566,335 total patients on Accutane.

(Please refer to Graphs in attached worksheet)

The total number of Accutane patients are growing faster than new patients (refer to Graph 1). This suggests that the duration of therapy is increasing over time. In 1996, a pilot Acne awareness DTC campaign was launched. Up to this point, a widening gap in male and female patients can be observed in Graphs 2 & 3 for New and Total Accutane patients respectively. The female share of Accutane patients has historically been higher than that of males - in the peak gap of 1996, the patient shares for males and female were 55% and 45% respectively. Subsequent years have seen a closing of this gap, and, in 1999, the total patient pool was split exactly in half. This can be viewed, in part, as a result of the DTC campaign that is targeted towards teen males. Graph 4 shows that teen groups (12-19 years old) make up the lion's share of Accutane patients, and have increased significantly in the last four years as a result of the male teen targeted DTC program. The teen male patients have increased by over 25% between 1998 and 1999. This group is also the fastest growing one of all patient groups.

Beginning in 1997, consumers became an important promotional target regarding acne therapy. This trend is expected to continue throughout 2000 and beyond. From the beginning, the objective of Roche's direct to consumer (DTC) non-branded acne campaign was to drive untreated acne sufferers to seek therapy from a doctor. The acne awareness DTC campaign targets the teen male audience, and their moms, because young men suffer from more severe acne, with a longer duration, than their female counterparts, and because moms are generally the key decision makers in the household. In addition, research shows that males are less likely to seek medical treatment for acne than females. Additionally, NDTI data clearly shows acne diagnosis visits for males increased at a faster rate than females in 1998, and actually surpassed those of females in 1999.

Managed Care:

Managed Care is increasingly taking an important role in this therapeutic area. Almost 89% of the Derms participate in Managed Care Plans. Increasing numbers of Derms (51% in 1999 from 44% in 1998) indicate being influenced by formulary restrictions for prescribing acne products to their managed care patients. Accutane is available on 93% of the formularies, of which 86% is unrestricted

while 7% is restricted. 70% of all Acne prescriptions in 1999 were covered by private insurance. 22% of the prescriptions were cash patients. Compared to the Acne market, Accutane private plan reimbursement is 87.5% of all prescriptions, while 11.3% is cash.

FDA:

In February 1998, Roche and the FDA concluded a year-long dialogue on the issue of psychiatric disorders in patients treated with Accutane. The scientific inquiry and subsequent negotiation resulted in an additional warning in the Accutane label which states, in part, that "Accutane may cause depression, psychosis, suicide attempts, and, rarely suicide." Although there was extensive media coverage in reference to the label change, prescribers were apparently unmoved by this information. Therefore, it did not have a subsequent negative effect on prescribing habits. While primary research conducted earlier in 1998 revealed that dermatologists were previously aware of the potential for mood changes in Accutane patients (stated in the package insert since 1986), they felt the nature of the disease state itself may predispose severe acne patients to be a population at risk for depression. Additionally, those physicians interviewed who had also treated a patient experiencing depression while on Accutane, could identify confounding factors in the patient's personal or medical history.

Ongoing surges of negative publicity continue in the press, both domestically as well as internationally, fuelled primarily by a father in Ireland, who continues to express desire to blame the death of his son on depression "associated" with his teen's use of (Ro)Accutane. An organization has been formed by the father called R.A.G.E. (Roaccutane Action Group Enforcement) with periodic meetings, a newsletter, and a website. The Accutane Medical Excellence team worked swiftly to handle the situation regarding these issues as they arose and on an ongoing basis looks towards ways of handling these types of situations more proactively.

In addition to psychological issues, adverse events associated with the use of Accutane, also continue to be under FDA scrutiny. To that end, the approval of the present rewrite of the Accutane package insert (including modifications to Adverse Events, Precautions and Warnings sections), has been prompted by a request by the Agency. The total label modernization, including PPP inclusion, is expected in April 2000.

It is an FDA requirement that an Action Letter regarding the approvable nature of the Accutane new formulation be sent to Roche by October 31, 2000. Futher, due to the wealth of product label revisions which are being conducted on the currently marketed product label, it is both anticipated and assumed that any further label changes will be additive to these changes, which should result in some "economies of time", regarding final new formulation label approval. These activities would greatly assist in realizing the goal of making the March 2001 launch of Accutane new formulation possible.

A. Patient Dynamics ... continued



B. Major Competitors/Mkt. Definition & Mkt. Share

Market Definition:

Accutane continues to be the only effective therapy for the management of severe recalcitrant cystic acne since the product was introduced in 1982. With no direct competitors, Accutane use continues to grow as patient visits and Accutane mentions increased significantly in 1999 (20%+).

While Dermatologists treat significantly more severe acre patients than the primary care specialities (GP/FP/IM) combined (21% of all patients for derms compared to 13% for PCPs in 1999), an increasing number of mild and moderate patients are seeking acre treatment with the PCPs. As expected. PCPs treat significantly more new acre patients than dermatologists. About one third of PCP acre volume is comprised of new patients, compared to less than one quarter of dermatologists' acre patients. Of acre patients treated with all therapy types, the severity of acre is broken out as follows:

	Dermatologists	Primary Care Physicians
Severe Acne	21%	13%
Moderate Acne	49%	43%
Mild Acne	30%	44%

Since dermatologists see more severe acne patients than primary care physicians, it is not surprising that they would also prescribe more Accutane. In fact, in 1999 dermatologists accounted for more than three quarters of all Accutane prescriptions (77%) - changing little over the previous year. Primary care specialities accounted for 10% of Accutane prescriptions in 1999, a 2% increase compared to 1998. The remainder of Accutane prescriptions were divided in very small percentages among a diverse range of specialities. Examples include OB/GYN and pediatrics, accounting for less than one percent respectively.

Accutane was prescribed to just under 574,120 patients in 1999. Last year, 50.7% of Accutane use occurred in female patients, while males accounted for 49.3%. Teens between 12 and 19 years of age accounted for more than half of Accutane patients, while adults between the ages of 20-39 years accounted for 30%. Males make up slightly less than half of the Accutane new patient population. Among teens (12-19 years old) however, males comprise 65% of patients, an increase of 1.5% over the previous year.

Double digit prescription growth was first reported for Accutane in 1996 at 12%. This trend continued in 1998 and 1999, each demonstrating a year-end total prescription increase of 14% and 10.3%, respectively. Total prescriptions have continued this trend through the first quarter of 2000, growing 6% over the same period last year.

Factors influencing Accutane growth include the impact of a dedicated dermatology sales force, and effective implementation of professional and consumer promotional programs. The number of

Accutane presentations for 1999 totalled 67,800. This represents an increase of 7% over 1998.

Market Share:

The market for treatment of severe recalcitrant cystic acne contains no true competitors to Accutane. It is a highly efficacious product, and re-treatment rates are minimal when Accutane is dosed appropriately. Bacterial resistance, a concern among leading antibiotic treatments (18% occurrence), is unlikely to develop with Accutane. Because of this product feature, one strategy being initiated in 2000 is to ensure that Accutane is positioned in "reasonable" acne treatment algorithms within the Managed Care business segment, so as to limit patient exposure to multiple courses of systemic antibiotics, and potentially facilitate an "earlier" trial of Accutane.

The anti-acne treatment category includes:

- topical agents (such as oral retinoids, antibiotics and benzoyl peroxides)
- c systemic products (chiefly anti-bacterial drugs) and oral contraceptives

Growth of the acne market, measured in terms of acne diagnosis visits, has been relatively small, with an increase of 4-6% over the past three years.

Status of Current Acne Agents

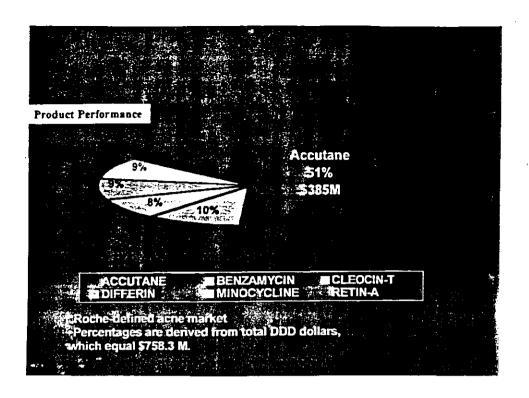
Dermatologists are more satisfied with available drug therapies for mild and severe acne, while moderate forms present their greatest treatment challenge. In contrast, PCPs are more satisfied with current therapies for mild acne, and are much less satisfied with those available for severe acne.

Use of topical retinoids by dermatologists has increased over the past year. Differin and Retin-A Micro are brands most preferred, specifically when prescribed in a cream or gel form. These agents are primarily chosen because they are effective with less irritation. Use of Differin has increased more than any other product compared to last year, and use of Retin-A has declined as it has been replaced by Retin-A Micro and by pharmacy generic versions (first generic out in1998 which are sold at approximately 50% of the brand price). Additionally, dermatologists anticipate an increase in their use of Avita, Klaron and Tazorac. Among oral antibiotics, Minocycline and Tetracycline (generic) are most preferred. Physicians select them because of therapeutic and cost efficacies.

Acne Market: Snapshot of Performance

Sales activity for Accutane was compared against the products listed below. They are not direct competitors, but have high usage patterns in the treatment of acne. Within the acne market (as defined by Roche), total DDD dollars grew 4.7% between 1998 and 1999.

Classification	DDD (SMM) FY 1999	DDD (\$MM) FY 1998	% Change	1999 % Share of DDD Market
oral retinoid	\$384.7	\$348.1	+10.5%	50.7%
topical retinoid	\$6 6.2	\$59.1	+12.0%	8.7%
topical retinoid	\$103.4	\$116.8	-11.5%	13.6%
systemic antibiotic	\$ 65.2	\$72.5	-10.1%	8.6%
topical antibiotic	\$59.7	\$58.9	+1.4%	7.9%
topical cream	\$79.1	\$ 68.7	+15.1%	10.4%
	topical retinoid topical retinoid topical retinoid systemic antibiotic topical antibiotic	FY 1999 oral retinoid \$384.7 topical retinoid \$66.2 topical retinoid \$103.4 systemic antibiotic \$65.2 topical antibiotic \$59.7	FY 1999 FY 1998 oral retinoid \$384.7 \$348.1 topical retinoid \$66.2 \$59.1 topical retinoid \$103.4 \$116.8 systemic antibiotic \$65.2 \$72.5 topical antibiotic \$59.7 \$58.9	FY 1999 FY 1998 oral retinoid \$384.7 \$348.1 +10.5% topical retinoid \$66.2 \$59.1 +12.0% topical retinoid \$103.4 \$116.8 -11.5% systemic antibiotic \$65.2 \$72.5 -10.1% topical antibiotic \$59.7 \$58.9 +1.4%



B. Major Competitors/Mkt. Definition & Mkt. Share ... continued

C. Customer Segments

The most significant Accutane customers are *dermatologists*. In 1998, as in the previous two years, dermatologists accounted for 77% of all Accutane prescriptions written. The majority of dermatologists (96%) prescribe Accutane to approximately 12% of their acne patients. Satisfaction with Accutane as a proven effective therapy for severe acne is demonstrated by a patient discontinuation rate of only four percent. Further increase in Accutane use will come from current prescribers, since very few dermatologists have no experience with the product (less than 1%).

In contrast, primary care physicians comprise the second highest Accutane user group, accounting for 10% of all Accutane prescriptions in 1999. As previously stated, the remainder of Accutane prescriptions are widely distributed in small percentages over a large variety of specialties.

Market research shows that the majority of dermatologists (89%) and PCPs (86%) participate in at least one managed care plan. Like the previous year, in 1999, Derms reported a higher proportion of HMO patient volume than PCP's. A sizeable portion of both dermatologists and PCPs (51% and 50% respectively) state that restrictions imposed by HMOs and PPOs have a growing influence in their choice of acne products to prescribe. This is a considerable increase from 1998's response of 44% and 46% for Derms and PCPs respectively. About 29% of the Derms and 40% of the PCPs indicate that their use of Accutane is restricted by managed care.

While the majority of acne patients have coverage for medication through private health insurance (including indemnity, HMOs, PPOs, etc.), there is still a sizeable proportion of patients with no prescription reimbursement plan. Less than one quarter of patients have no prescription coverage. Prescription coverage for acne patients is depicted below:

	Dermatologists	Primary Care Physicians
Private Health Insurance	70%	65%
Medicaid	8%	14%
No Insurance	22%	21%

Consumers are another key segment of Accutane customers. In 1999, acne awareness DTC promotion continued to focus on driving male teens into the doctor's office. Teenage boys and men suffer from more severe forms of acne, and in many cases their condition persists longer than acne conditions experienced by teenage girls or women.

There were over 209,000 new male Accutane patients in 1999, an increase of 16.6% over 1998. Female patients numbered nearly 216,000, an increase of 8.3% over last year. Similarly, NDTI data shows that acne diagnosis visits grew 12.8% in 1999 compared to 1998, which was the largest increase of visits over the last 6 years - indicating that many more patients are visiting a physician for acne consultation. It is important to note that in addition to Roche's non-branded acne campaign, several other dermatology products began DTC advertising programs in 1999 (both branded and unbranded), and have undoubtedly contributed to the overall increase in visits.

When the overall number of acne diagnosis visits are broken out by gender, males accounted for 41% of all visits. However, male visits are growing at a much faster rate (16% in 1999 over 1998) than female visits (10% over the same period). The fact that male patients are both seeking treatment for acne, and are being treated with Accutane at an increasing rate compared to their female counterparts, suggests that the DTC acne campaign is having its desired effect.

Results of a tracking study regarding the 1998-1999 unbranded acne direct to consumer advertising campaign shows that teens and mothers whose sons have acne are well aware of acne advertising and, as such, contribute greatly to ad-related calls to action. Prompted ad-awareness was 46% in a survey of consumer teens and mothers whose sons have acne following exposure to non-branded print and television advertising.

An ROI analysis of the Acne 1999 (Spring and Fall) campaign was conducted utilizing three different study methodologies: (1) a point in time study, (2) an advertising agency model, and (3) a statistical regression analysis. While study results varied from one model to the next, they each concluded that a favorable ROI for the Acne DTC campaign, which approximates a 3:1 ratio, exists. The statistical regression analysis provided further indication that the most efficient use of promotional funds, in order of ROI, was sales force, print and TV.

In Fall of 1999, the DTC campaign was guided with a 'buy management' process which addressed the needs to:

- 1. Increase the number of completed calls
- 2. Grow business by tapping into various market segments, such as ethnic and age groups

The learnings from the Fall 1999 campaign were applied to the roll-out of a fresh, new Acne DTC campaign in the Spring of 2000. As a direct result of this combination of buy management process and the new Acne DTC program, the calls from the Spring 2000 TV campaign have increased by over 40% compared to the Fall 1999 campaign.

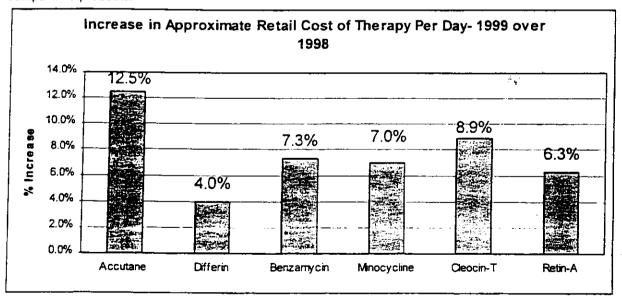
C. Customer Segments ... continued

D. Pricing Trends

Since January 1997 to date (March 2000), there have been 13 price increases totaling 48.2%. In 1999 alone, price increases totaled 10.3%. The formulary status and reimbursement profile for Accuatne has been discussed previously under Part C of the Situational Analysis (Customer Segments). The daily consumption of Accutane as a brand changed little in 1999 over 1998. The only exception was 20MG, the daily consumption of which increased by 2% over 1998. The total therapy days per prescription rose by about 2% in 1999. The largest increase in therapy days per prescription was seen in 10MG, which increased by approximately 4% over 1998. The only area of true growth was seen in the total therapy days for Accutane. Consistent with the last three years, Accutane total therapy days grew by about 16% in 1999. This means that patients are staying on therapy longer than they have before. More specifically, the biggest therapy duration increases came from 20MG and 40MG, respectively. This increase in the total number of days of therapy is another major factor that has contributed to the success of Accutane, and the tremendous growth in prescriptions. (Note: The 40MG SKU is the largest selling strength - representing over 70% of all Accutane sales.)

Product launch pricing for Accutane new formulation will be a significant factor in completing the successful market conversion from the currently marketed formulation. (Note: As previously mentioned in this document, the complete Accutane New Formulation Product Launch Plan will be scheduled for a mid-year presentation to the BOG.)

The overall cost of Accutane therapy increased by 12.4% in 1999 over 1998. Even though the cost of therapy has consistently increased over time, there is very little impact on the growth of prescriptions. The following graph shows increases/decreases in average retail cost of therapy per day across all comparable products:



D. Pricing Trends ... continued

E. Revenue Driver Key Assumptions

Assumption: Pregnancy Prevention			· ·
Validation	Additional Validation	Risk	
Though voluntary, the FDA may require PPP. PPP provides a barrier to generics.	Inclusion of PPP in the current Label. Interaction of FDA's Derm Division and OGD to insure that PPP becomes a labeling requirement for ANY oral Isotretinoin.	Moderate	

Assumption: Physician Prescriber Program Validation	Additional Validation	Risk
While Primary Research shows that Roche Derm Reps provide the finest patient and physician education materials, they lag in providing adequate detailing. This is primarily as a result of significantly fewer Roche Derm rep FTE's as compared to other Derm companies. Roche is the #1 Derm company (revenues) at a fraction of the details of the nearest competition	Physician Detailing Audit confirms relative detailing levels among Derm companies	Unknown: It is extremely difficult to attempt to predict the effect in prescriptions as a result of a lower level of Accutane details (vs. other Derm companies). Without research to attempt to quantify the effect of increased details, the true effect of additional details cannot be known. Moderate to High: Increasing the level of Detailing may reveal additional, previously untapped revenue potential.

Assumption: DTC Acne Campaign		
Validation	Additional Validation	Risk
Historical Accutane data shows strong relationship between DTC campaign and units sales	Analysis of secondary data from callers proves that better targeting improves the revenue potential of the product RCL Point-in-time study - Statistical Regression Analysis - ROI Analysis (3 methodologies)	High: Increased units sales are very sensitive to DTC spending levels

Assumption: Accutane New Formulation Conversion		
Validation	Additional Validation	Risk
Primary research is underway to investigate appropriate conversion from existing to new formulation.	Secondary research from analog models suggests that early and proper conversion of line extension products is needed. Market conversion from Tegison to Soriatane indicates the importance of increasing product detailing level and it's correlation to facilitating rapid market conversion.	High: Delayed/Slow and/or improper conversion of the formulation will have significant short and long term effects on the revenue. Rapid physician conversion and rehabitutaion to the new Accutane formulation will serve to slow the rate of generic penetration, when available in the marketplace.

Assumption: General Product Support		
Validation	Additional Validation	Risk
Primary and Secondary research shows that professional affiliations and programs (such as AAD and CME) have a desired positive effect on units sales.		Moderate: Activities serve to reinforce the position of Roche as a leader in Dermatology, and and the Accutane brand as the "Gold standard" for SRNA.

F. Product Performance Overview

<u> </u>	1999 Full Year Actual	2000 YTD Actual	2000 YTD Budget	Variance 2000 YTD Actual v. Budget	2000 Annual Budget	2000 LE	2000 LE vs. 1999 Full Year Actual
Net Sales	\$469,318	\$117.977	\$115,464	2.2%	\$562,800	\$600,000	27.8%
Mkt.Share	-			0.0 p.p.			0.0 p.p.
Scripts							
Number	1,877	426	420	1.4%	2.061	2.061	9.8%
Share %				0.0 p.p.			0.0 p.p.

G. SWOT Analysis

• Strengths and Weaknesses including attitudes and perceptions

Strengths	Weaknesses
Accutane has no true direct competitors for the treatment of severe recalcitrant cystic acne	Teratogenicity in women and the potential for hepatotoxicity remain the primary safety concerns despite both the 1998 FDA-mandate for depression-related product labeling changes, and the recent FDA request for changes to the Adverse Events and Warnings section of the PI
Accutane is highly efficacious with minimal re-treatment rates when dosed appropriately	The high incidence of mucocutaneous side effects (dry lips, eyes, face, etc.) remains the most troublesome side effect experienced by patients
No product in the anti-acne category works as effectively as Accutane	Recent research indicates that mucocutaneous effects do not present a barner to physician use of Accutane, and rarely leads to patient discontinuation (4%).
There is no indication that bacteria, resistance is developing against Accutane	It is important to note that since January 1997, there have been eleven price increases, totaling 48.2% (10.3% of this increase came in 1999 alone). Almost 15% of all Accutane prescriptions are covered by cash
Accutane has strong support by dermatologists for its professional promotion and PPP	The potential for further restrictions on Accutane prescribing by dermatologists continues to grow as almost a third of the dermatologists (29%) reported limitations when prescribing Accutane in 1999 compared to 19% in 1998.
Additional years of product use continue to increase the comfort level among dermatologists and primary care physicians who prescribe Accutane	New Formulation prescriptions are likely to reduce the overall consumption of units with once-a-day dosing, thus the launch pricing strategy for this product is critical.
The number of patients receiving the brand continues to grow	
Once-a-day Accuatne new formulation dosing with a reduced milligram to milligram side effect profile would encourage and facilitate market conversion.	
Roche's Derm Physician and Patient support programs are unparalleled in the acne therapeutic area, and recognized as such.	

G. SWOT Analysis ... continued

Opportunities and Threats (current and future)

Opportunities	Threats
Current sales messages specifying appropriate use of Accutane targeted at physicians may pave the way for the new formulation (BID dosing, taken with food)	Regulatory scrutiny will continue and may intensify
Consumers need more information about acne, and about the importance of seeing a physician for the treatment of acne	Increasing cost pressures may lead to greater restriction by managed care organizations
Untreated acne sufferer customer base is highly aware of and responsive to DTC advertising calls to action. Additionally, customer segment marketing (i.e. ethnic) provides a real opportunity to expand, establish and provide product loyalty to "new" customer bases.	Failure to gain regulatory approval for inclusion of the Roche Pregnancy Prevention Program in the Accutane product label would place the franchise at risk
Proactive revisions to the Accutane Pregnancy Prevention Program (PPP) are in progress, with a planned "complete" implementation date of 7/00	Failure to gain regulatory approval for a new Accutane once-daily formulation in a timely fashion (1Q00) would put the franchise at significant risk.
Reinforcement of the Roche image as a leader in dermatology within the medical community can be accomplished by focusing on promotional detailing and key customer relationships	Dermatologists' perception of the new Accutane once-daily formulation may not be as favorable as desired (recent research suggests that 50% of physicians already dose Accutane QD)
Accutane has a dynamic multi-faceted life cycle plan	Failure to gain regulatory approval for Accutane Pediatric Exclusivity extension in a timely fashion (prior to 4Q01) would place the franchise at risk
Launch, possibly through partnership, a formulation of the currently marketed Accutane product as a branded generic. Prior to patent expiration of current Accutane, explore a variety of scenarios which include launch of branded/ pharmacy generic, with/ without a derm partner.	Potential for branded/ pharmacy generic entries exists following Accutane patent expiry on February 2002 when Pediatric exclusivity is granted.
Product conversion of Accutane to Accutane new formulation may be accelerated/ facilitated through one of the following methods: - increase derm sales force head count 70 FTE vs 35 - co-marketing/ co-promotion with a complimentary well-known derm company	

04. Business Objectives and Measurements

A. Base Case Revenue Forecast

Net Sales: product revenue, current and projected

	2000 LE	2001 Budget	2001 Plan Yr One	2002 Plan Yr Two	2003 Plan Yr Three	2004 Plan Yr Four	2005 Plan Yr Five
Net \$	600,000	622,000	622,000	500,000	410,000	350,000	300.000

Percent Comparison

	2001 Budget	2001 Plan vs. 2000 LE	2002 vs. 2001	2003 vs. 2002	2004 vs. 2003	2005 vs. 2004
Net \$	3 7%	3 7%	(19.6%)	(18.0%)	(14 6%)	(14.3%)

A. Base Case Revenue Forecast ... Continued

General Base Case Revenue Assumptions:

- 1. Returns are assumed at 2.1% of invoice sales each year
- 2. Chargebacks are assumed at 1.1% of invoice each year
- 3. Medicaid Rebates are assumed at 1% of invoice each year
- 4. Total oral Isotretinoin market growth is assumed at 0.9% for each year.
- 5. The price assumptions are as follows: (IMPORTANT NOTE: Parity pricing at the "per capsule" level is assumed.)

		,			3 N	
10MG 100's	\$458.30	\$472.05				
20MG 100's	\$543.47	\$559.77				<u> </u>
40MG 100's	\$631 41	\$650.35				
7.5MG 30's		\$130.21	\$134.12	\$138.14	\$142.28	\$146.55
15MG 30's	- :	\$130.01	\$133.91	\$137.93	\$142.07	\$146.33
22.5MG 30's	į	\$128.56	\$132.42	\$136.39	\$140.48	\$144.70

Annual Base Case Revenue Assumptions:

2001

- 1. Total Accutane brand (Current and new formulation) production units increase by 39% (ramp up to maintain inventory levels of 2 MOH)
- 2. Accutane new formulation is launched March 2001
- 3. Accutane new formulation converts 100% from original Accutane formulation (4/1/01 thru 1/31/02)
- 4. Roche granted Pediatric Exclusivity for Accutane extending patent life through 2/8/02
- 5. Total Accutane patient increase of 14%
- 6. Standard 2% annual effect of net price increase occurs
- 7. Annual contract rebate of 1% is assumed.

2002

- 1. Total Accutane new formulation units decrease by 20% due to generic market entrants (branded and unbranded) Generics eligible to enter market 2/08/02
- 2. Total Accutane patient decrease of 21% is assumed
- Standard 2% annual effect of net price increase occurs
- 4. Annual contract rebate of 2% is assumed

2003

- 1. Accutane ID launched 4Q03 (No pipeline fill is assumed)
- 2. Branded Accutane market converts to ID formulation at the expense(cannibalization) of Accutane new formulation.
- 3. Total combined Accutane (new formulation and ID) brand units decrease by 20% due to generic market entrants (branded and unbranded)
- 4. Total Accutane patient decrease of 20% is assumed

- 5. An estimated annual net price increase of 5% occurs
- 6. Annual contract rebate of 5% is assumed

2004

- 1. Total combined Accutane (new formulation and ID) brand units decrease by 17% due to generic market entrants(branded and unbranded)
- 2. Total Accutane patient decrease of 17% is assumed
- 3. An estimated annual net price increase of 7, 5% occurs
- 4. Annual contract rebate of 7.5% is assumed

2005

- 1. Total Accutane ID brand units decrease by 17% due to generic market entrants(branded and unbranded)
- 2. Total Accutane patient decrease of 17% is assumed
- 3. An estimated annual net price increase of 10% occurs
- 4. Annual contract rebate of 10% is assumed

04. Business Objectives and Measurements

B. Base Case Product Expenses

Expenses by M1 Major Family

Years	Promotion	DTC'	Prof. Programs ²	Medical Affairs ²	Product Support	Field Programs	Launch Meetings	CT&D'	SubTotal	Field Force	Total
2000	8,547	10,726	2,412	2,300	3,219	314	250	24	27,792	0	27.792
2000% Total	30.8%	38.6%	8.7%	8.3%	11.6%	1.1%	0.9%	0.1%	100.0%	0.0%	100%
2001	11,095	10,976	3,404	2,700	4,412	520	1,750	40	34,897	O.	34,897
2001% Total	31.8%	31.5%	9.8%	7.7%	12.6%	1.5%		0.1%	100.0%	0.0%	100%
2002	9,907	10,251	2,245	2,750	3.853	365	250	40	29,661	<u>D'i</u>	29,661
2003	8.894	8.161	1,920	2,000	3.678	365	250	40	25.308	C:	25,308
2004	7.678	5,351	1,370	2.000	2,662	365	250	40.	19,716	C.	19,716
2005	6.833	3.355	1,370	2,000	2,612	365	250	40	16.825	C.	16.825

Notes:

- Direct To Consumer Campaigns.
- 2 Medical affairs and professional program spending should tie to the spending levels outlined in the Integrated Medical Strategic Plan.
- 3 The Meeting Planning and Career Training & Development departments should provide costs for Launch Meetings and CT&D, respectively.
- 4 The Primary Care or Specialty Care Finance Director should provide the cost per field force presentation used to calculate total field force costs.

04. Business Objectives and Measurements

C. Revenue Sources

Market Growth

Assumption 1:	Severe acne sufferers increase by 6%+ as the DTC campaign increases awareness of acne
Assumption 2:	Continued greater increase in the number of new male patients vs new female patients.
Assumption 3:	The convenience of once-a-day dosage and lower side effects profile on a "mg to mg" comparison of Accutane new formulation vs. Accutane, serves to facilitate market conversion and provide an overall increase in usage due to the expected improvement in patient compliance.

← Share Shift.

Assumption 1:	Continued displacement of Oral Antibiotics as doctors see better and more effective results through earlier and more aggressive patient treatment with Accutane.
Assumption 2:	Continued displacement of Retin-A for the treatment of Severe Acne
Assumption 3:	

Value Premium

Assumption 1:	Accutane is the ONLYchoice of therapy in its class for the treatment of severe recalcitrant nodular acne. The premium Retail Cost Of Therapy per Day for Accutane has had little effect on the prescribing behavior.
Assumption 2:	
Assumption 3:	

C. Revenue Sources ... continued

04. Business Objectives and Measurements

D. Variance and Sensitivity - Critical Revenue Drivers

Key Assumptions/ Revenue Driver	Ability to influence via Marketing Initiatives	Possible Range (Year Three)	Rational for Range	Revenue Impact (Year Three)	Critical Marketing Initiatives
Pregnancy Prevention	2	-10% to 0%	The PPP program serves only to delay the entry of generics to the market should it become a mandatory part of the product label.	-\$41MM to \$0	Detail Aids PPP Kits
Accutane New Formulation Conversion	1	-10% to 0%	Product is launched in March of 2001 and has been in the market for a period of 21 months (as of 1/1/03)	-\$41MM to \$0	 ▶ Medical Affairs ▶ Promotion Rebates
Physician Prescriber Program	4	-25% to 10%	Aggressive detailing of a branded generic by a well known, well-established derm company can have a significant negative impact. Aggressive detailing by Roche derm reps (enhanced field programs plus incentivized selling) can result in a positive revenue stream	-\$103MM to +\$41MM	F Promotion Sales Force Direct Mail
DTC Acne Campaign	4	-10% to 0%	Failure to maintain a direct to consumer campaign when a branded generic is available in the marketplace will result in accelerated Accutane brand erosion	-\$41MM to \$0	 ▶ Print Media ▶ Electronic Media
General Product Support	3	-3% to +3%	Maintain repoire with dermatologists and the rest of the professional community	-\$12.3MM to +\$12.3MM	Medical AffairsProfessional Programs

Legend:	
Scale is 0 to 4 where 0 = Least and 4 = Most.	

A. Marketing Initiatives

Support PPP as a Barrier To Generic Entry

Reference Title:

Pregnancy Prevention

Initiative Number:

1

• ' Goal

The Pregnancy Prevention Program provides a barrier to entry for generic entrants. Additionally the Roche PPP may be adopted by the FDA as a label requirement for all oral isotretinoin.

- Description.
- Modified PPP kit
- Modified Detail Aids
- Tactics
- 1. PPP Update including: Contraception Hotline, and Videotape, Urine Pregnancy Tests
- 2. CME programs for MD's and R. Ph.'s & NP's
- 3. PPP update in multi-languages

Performance Measures and Potential ROI Tracking

Potential for revenue preservation at time of generic (Branded/unbranded) product launch(es)

A. Marketing Initiatives

Successful Launch and Conversion for Current Accutane to Accutane New Formulation

Reference Title:

NF Conversion

Initiative Number:

2

Goal

Proper and timely conversion to the Accutane new formulation will likely result in slower generic penetration, when generics(branded/unbranded) to the "older" strengths are eligible to become available in the marketplace(2/8/02). Additionally, the once-a-day formulation, reduced side effect profile on a "mg to mg" basis and "no food effect" product attributes will serve to increase the number of units through "better" patient compliance.

Description

Medical Affairs

 Highlight the key benefits of Accutane new formulation over current Accutane. These would be incorporated as part of the launch copy platform, and thus become essential to the detailing effort to communicate these key product benefits to the physicians

Promotion

- Where possible, incorporate the benefits of Accutane new formulation into the DTC campaign.
- Use of Pharmacy CE, Pharmacoeconomic study data and other value added programs in the MC setting.

Rebates

Facilitate prescription coverage by MCO's through contract rebates.

Tactics

Some of the tactics that would be incorporated for the successful launch of the New Formulation include:

- 1. DTC campaign
- 2. CMEs and AAD
- 3. Field Programs
- Field Support

Performance Measures and Potential ROI Tracking

- 1. Qualitative Feedback
- 2. Primary research
- 3. Number of Sales calls
- 4. Tracking on conversion models through prescriptions and sales
- Track/quantify the number of MCO's with Accutane new formulation on formulary, and without restriction

A. Marketing Initiatives

Re-Emphasize Roche as a leader and the Accutane Brand (including new formulation/ID) as the "Gold Standard" in SRNA

Reference Title:

Physician Prescriber Program

Initiative Number:

3

Goal

- 1. To re-emphasize Roche as a leader and the Accutane Brand as the "Gold Standard" for SRNA
- 2. To successfully launch the New Formulation and facilitate the rapid conversion from Old Formulation.

Description

- Promotion: Promote New Formulation through enhanced levels of product detailing and appropriate physician and patient education materials
- 2. Sales Force: Increased overall detailing effort (Derm rep headcount) to better support the launch of the new formulation re-establishing. Roche as a leader in Dermatology.
- 3. Direct Mail: Provide appropriate patient education materials regarding new formulation(i.e. Efficacy, Dosing,, etc.)

Tactics

- 1. Professional journal ads
- 2. Dermatologists' counseling kit
- Performance Measures and Potential ROI Tracking

A. Marketing Initiatives

Increase Patient visits to Doctor Through Increased Acne Awareness

Reference Title:

DTC Acne Campaign

Initiative Number:

4

Goal

Increase consumer awareness of acne as a treatable and "curable" disease through the unbranded DTC campaign. This will serve to increase the size of the acne market, resulting in proportional increases in Accutane usage by severe acne patients.

Description

DTC promotion is the most effective way to increase the awareness of acne. Increased awareness has historically shown to increase the number of severe acne patients using Accutane.

Tactics

- 1. Print Media
- 2. Electronic Media: TV and Internet

Performance Measures and Potential ROI Tracking

Existing DTC tracking study, that measures 800# callers, (from DTC response) conversion to patient, and eventually to Accutane prescription, has been instrumental in developing ROI by not only media type, but also by media sources.

A. Marketing Initiatives

Establish Roche as a Dermatology as a Leader in the Medical Community

Reference Title:

General Product Support

Initiative Number:

-5

Goal

Support functions that serve to establish Roche in the Dermatology community.

Description

Key activities would include certain Medical (i.e. clinical trial) and Promotional programs (i.e. AAD,DNA support) in addition to other product support activities

Tactics

Tactics include, but are not limited to:

- 1. Grants/sponsorships (AAD)
- 2. New Formulation Publications
- 3. Roche sponsored Medical Affairs studies
- 4. DTC Public Affairs
- 5. PP&GA Activities

Performance Measures and Potential ROI Tracking

B. How Marketing Initiatives Influence Decision Makers

	Size of Audience	Relative Importance to Influence	Marketing Initiatives	Tactics/Promotional Levers and Relative importance	Rationale
Patient decides to seek treatment	1,016	19	DTC Acne Campaign	DTC 4	Acne is not debilitating to the point that one must go to the doctor
Patient decides to ask for Accutane	640	19		Non-Branded DTC	Accutane is the ONLY drug for severe acne
Patient willing to pay out of pocket	72	a		Pncing 0 DTC 2	Patients will want generic
<u> </u>	Patient Subtotal:	38			
MD decides to treat	9.198	10	Physician Prescriber Program General Product Support	Symposia 4 Publications 1 Phase IIIB/IV 0 Product Label 1 Sales Force 4 Non-Personal Promo 2	If MD undertreats, patients will drop out of therapy
MD decides to treat w/ drug in same class	7,795	19	Physician Prescriber Program General Product Support	Symposia 4 Publications 1 Phase IIIB/IV 0 Product Label 1 Sales Force 4 Non-Personal Promo 2	Doctors may be over-treating with systemic anti-biotics
MD decides to treat with Accutane	7,795	19	Physician Prescriber Program General product Support	Symposia 4 Publications 1 Phase IIIB/IV 0 Product Label 1 Sales Force 4 Non-Personal Promo 2	MD sees advantages to treating with QD/NF Brand
	MD Subtotal:	48			, <u> </u>
Product is covered by payor		14		Contracted Sales	MDs may not write Rx for uncovered patients

B. Decision Makers (more detailed) ... Optional

This optional table provides the opportunity to expand the decision makers (i.e. sub-specialties of MDs, multiple types of payors). Complete the table according to the help provided for the table above.

Decision Makers	Size of Audience	Relative importance to influence	Marketing Initiatives	Tactics/Promotional levers and relative importance	Rationale
					<u> </u>
					· · · · · · · · · · · · · · · · · · ·
					1

Legend:
Scale is 0 to 4 where 0 = Least and 4 = Most.

Include commentary as well as relevant exhibits below. Insert page breaks as needed via menu Create > Page Break.

06. Integrated Medical Strategic Plan



A. Marketing Initiatives Investment Summary

Marketing Initiatives	Description of Major Expense Areas	2001 Investments (Year One)	2002 Investments (Year Two)	2003 Investments (Year Three)
Pregnancy Prevention	PPP kit. Urine pregnancy test, Contraceptive Counselling and Videotape	\$5.430	\$4,512	\$3,867
NF Conversion	Launch in 2001, Publication strategy, CME: MD, RN & R.Ph.	\$8,045	\$4,646	\$2,360
Physician Prescriber Program	Professional Literature and Aids, MD/ Patient teaching tools	\$3,836	\$3,296	\$4,504
DTC Acne Campaign	New creative annually for Broadcast and Print, Media space and Internet	\$12,126	\$11,401	\$9,011
General Product Support	Annual AAD convention, Marketing Intelligence activities, Medical Needs, Public Affairs and Public Policy & Government Affairs activities	\$5,460	\$5,806	\$5,566
· · · · · · · · · · · · · · · · · · ·		\$0	\$0	\$0
		\$0	so	\$0
		\$0	\$0	\$0
		\$0	\$0	\$0
	Investment Total:	\$34,897	\$29,661	\$25,308

Note:

This summary reflects total Base Case investments. Please refer to Section 10, Marketing Initiatives Summary Report to see total investments and comparisons.

B. Marketing Initiatives Investment Totals by M1 for Year 2001

Base Case

Marketing Initiatives	Promotion	DTC	Prof. Programs	Medical Affairs	Product Support	Field Programs	Launch Meeting s'	CT&D,	SubTotal	Field Force	Initiative Total
Pregnancy Prevention	3,941	O	1,300	o	189	Q	O	0	5,430	0	5,430
NF Conversion	2.251	0	969	2,500	535	0	1,750	40	8,045	0	8.045
Physician Prescriber Program	2,701	Ö	1,135	O	0	0	a	0	3,836	o	3,836
DTC Acne Campaign	1,150	10,976	ο	0	O	O	ä	0	12,126	0	12,126
General Product Support	1,052	o	ō	200	3,688	520	O	0	5,460	O	5,460
									0		0
									0		C
									0		C
	ī								0		0
M1 Total	11.095	10.976	3,404	2.700	4,412	520	1,750	40	34,897	0	34,897

- Direct To Consumer Campaigns.
- 2 Medical affairs and professional program spending should tie to the spending levels outlined in the Integrated Medical Strategic Plan.
- 3 The Meeting Planning and Career Training & Development departments should provide costs for Launch Meetings and CT&D, respectively.
- 4 The Primary Care or Specialty Care Finance Director should provide the cost per field force presentation used to calculate total field force costs.

B. Marketing Initiatives Investment Totals by M1 for Year 2002

Base Case

Marketing Initiatives	Promotion	DTC'	Prof. Programs	Medical Affairs ²	Product Support	Field Programs	Launch Meeting s'	CT&D,	SubTotal	Field Force	Initiative Total
Pregnancy Prevention	3,775	0	625	a	112	O		0	4,512		4,512
NF Conversion	1,811	0	585	2,250	0	0	٥	0			4.646
Physician Prescriber Program	2,261	0	1.035	O	O	0	0		3,296	0	3,296
DTC Acne Campaign	1,150	10,251	α	o o	O	0	o	0	11,401	0	11,401
General Product Support	910	0	Ö	500	3,741	365	250	40	5,806	0	5,806
									0		0
									O		
i									0		
M1 Total	9,907	10,251	2,245	2,750	3.853	365	250	40	29,661	a	29,661

- 1 Direct To Consumer Campaigns.
- 2 Medical affairs and professional program spending should tie to the spending levels outlined in the Integrated Medical Strategic Plan.
- 3 The Meeting Planning and Career Training & Development departments should provide costs for Launch Meetings and CT&D, respectively.
- 4 The Primary Care or Specialty Care Finance Director should provide the cost per field force presentation used to calculate total field force costs.

B. Marketing Initiatives Investment Totals by M1 for Year 2003

Base Case

Marketing Initiatives	Promotion	DTC'	Prof Programs	Medical Affairs ²	Product Support	Field Programs	Launch Meeting s ³	CT&D,	SubTotal	Field Force	Initiative Total
Pregnancy Prevention	3,405	0	350	Q	112	O	O	0	3,867	0	3,867
NF Conversion	275	0	585	1,500	O		α.	0	2,360	٥	2,360
Physician Prescriber Program	3,519	0	985	0	O	o	o		4,504	0	4,504
DTC Acne Campaign	850	8,161	0	0	o	0	0		9,011	0	9,011
General Product Support	845	0	0	500	3,566	365	250	40	5,566	,	5,566
- Juppon								-	0		0
				$\overline{}$	t				0		0
			-						0		C
									0		0
M1 Total	8,894	8,161	1,920	2.000	3.678	365	250	40	25.308	0	25,308

- Direct To Consumer Campaigns.
- 2 Medical affairs and professional program spending should tie to the spending levels outlined in the Integrated Medical Strategic Plan.
- The Meeting Planning and Career Training & Development departments should provide costs for Launch Meetings and CT&D, respectively.
- The Primary Care or Specialty Care Finance Director should provide the cost per field force presentation used to calculate total field force costs.

C. Marketing Initiative Investment Rationale

Marketing Initiatives	Rationale for Investment Level (Revenue Driver Effect, Supporting Data, Analogs)	Timing to Return (ROI)	\$ Impact on Later Year Funding
Pregnancy Prevention	Though voluntary, the FDA may require PPP. Greater PPP spending may provide barner to generic-spending, thus, spending is essentially required	Immediate	\$0
NF Conversion	Physician conversion will result in slower generic erosion. Spending (Professional materials, Salesforce, field programs) will drive rapid new formulation conversion.	Immediate and longer term (3 years)	\$212,000
Physician Prescriber Program	Spend needed for physicain detailing. Essential to re-emphasize Roche dermatology franchise as a leader, and the Accutane Brand as the Gold Standard in treating SRNA	lmmediate	\$10,000
DTC Acne Campaign	Historical Accutane data (DTC ROI Analysis) shows strong relationship between DTC spending and unit sales	Near and Mid-term	\$ 33,000
General Product Support	Essential to re-emphasize the Roche dermatology franchise as a leader in the professional Dermatology community	Near and Long-term	\$14,000
		b.	
Total			\$269,000

D. Marginal Investment impact

Marketing Initiatives	Relative Impact of Marginal Increase	Max Case Rationale	Relative Impact of Marginal Decrease	Min Case Rationale
Pregnancy Prevention	1	Increase in PPP Spend will only be beneficial if FDA makes PPP a labelling requirement for all isotretinoin. As a labelling requirement, PPP can serve as an effective barrier to delay generic entry, thus additional spend could be justified.	0	PPP spending cannot be reduced
NF Conversion	2	Conversion to NF is an aggressive goal in a relatively short time frame at the current spend level	4	Conversion MUST occur prior to availability of generic (branded/unbranded) isotretinoin in the marketplace
Physician Prescriber Program	2	Doubling of professional detailing over 2000 level is necessary to effectively and rapidly launch the New Formulation of Accutane	2	Doubling of professional detailing over 2000 level is necessary to launch the New Formulation of Accutane
DTC Acne Campaign	4	Increased patient pool	4	Decreased patient pool
General Product Support	3	Maintain/build repoire with dermatologists and the rest of the professional community	3	Maintain repoire with dermatologists and the rest of the professional community

Legend:			
Scale is 0 to 4 whe	ere 0 = Least and	1 4 = Most.	

A. Marketing Initiatives Investment Increase Summary

Marketing Initiatives	Description of Change and Rational for Max Level	2001 investments (Year One)	2002 Investments (Year Two)	2003 Investments (Year Three)
Pregnancy Prevention	FDA may require PPP as part of oral isotretinoin labelling, which may serve to delay market entry of a generic competitor. Inclusion of the PPP as a labelling requirement for all oral Isotretinoin serves only to defend Accutane revenues in the year of the competitive launch (2002).	\$456	\$181	\$40
NF Conversion	Rapid NF market conversion (i.e. adequate personal selling, professional promotion, C.E. and publications) is essential for preserving the revenue stream in future years	\$767	\$213	\$25
Physician Prescriber Program	Augments market conversion to NF (2001-2002) and continues to establish Roche as a leader in dermatology	\$582	\$863	\$ 575
DTC Acne Campaign	Increased DTC spending serves to drive more untreated patients into the patient pool resulting in a larger patient base for Accutane	\$1,885	\$1,018	\$1,060
General Product Support	Supports key activities to facilitate the conversion of current to new formulation.	\$479	\$175	\$ 215
		\$0	\$0	\$0
		so	\$0	\$0
		\$0	so	\$0
		\$0	\$0	\$0
	Investment Increase:	\$4,169	\$2,450	\$1,915

Note:

This summary reflects an Increase from Base Case, not total Max investments. Please refer to Section 10, Marketing Initiatives Summary Report to see total Max investments and comparisons.

B. Marketing Initiatives Investment Increases by M1 for Year 2001

Max Case: Increases from Base Case

Marketing Initiatives	Promotion	DTC.	Prof. Programs	Medical Affairs ²	Product Support	Field Programs	Launch Meeting s ³	CT&D'	SubTotal	Field Force	Initiative Increases
Pregnancy Prevention	87	0	300	a	69				456		456
NF Conversion	132	Ó	100	200	75	0	250	10	767		767
Physician Prescriber Program	282	o	300	O	0	Ö	a	0	582		582
DTC Acne Campaign	O.	1,885	o	o	O	0	0	0	1,885		1,885
General Product Support	73	a	o	0	306	100	0	0	479		479
									0		
									0		
M1 Increases	574	1,885	700	200	450	100	250	10		0	4,169

- Direct To Consumer Campaigns.
- 2 Medical affairs and professional program spending should tie to the spending levels outlined in the Integrated Medical Strategic Plan
- 3 The Meeting Planning and Career Training & Development departments should provide costs for Launch Meetings and CT&D respectively.
- 4 The Primary Care or Specialty Care Finance Director should provide the cost per field force presentation used to calculate total field force costs.

B. Marketing Initiatives Investment Increases by M1 for Year 2002

Max Case: Increases from Base Case

Marketing Initiatives	Promotion	DTC.	Prof. Programs	Medical Affairs ²	Product Support	Field Programs	Launch Meeting s'	CT&D3	SubTotal	Field Force	Initiative Increases
Pregnancy Prevention	116	a	50	o	15	O	0	0	101		181
NF Conversion	113	0	100	O.	O	0	0	0	213		213
Physician Prescriber Program	713	0	150	o	0	o	0	C	863	a constitution of the cons	863
DTC Acne Campaign	75	943	O	O	0	0	0	C	1,018		1,018
General Product Support	60	O	O	0	115	0	0	C	175	_	175
									0		- 0
-									0		0
M1 Increases	1,077	943	300	0	130	0	0	C	2,450		2,450

Notes:

Direct To Consumer Campaigns.

2 Medical affairs and professional program spending should tie to the spending levels outlined in the Integrated Medical Strategic Plan.

3 The Meeting Planning and Career Training & Development departments should provide costs for Launch Meetings and CT&D, respectively.

4 The Primary Care or Specialty Care Finance Director should provide the cost per field force presentation used to calculate total field force costs.

B. Marketing Initiatives Investment Increases by M1 for Year 2003

Max Case: Increases from Base Case

Marketing Initiatives	Promotion	DTC.	Prof. Programs	Medical Affairs ²	Product Support	Field Programs	Launch Meeting s ³	CT&D,	SubTotal	Field Force	Initiative Increases
Pregnancy Prevention	25	0	O	0	15	O	O	O	40		40
NF Conversion	25	0	O	O	0	0	0	C			25
Physician Prescriber Program	575	0	a	0	O.	O	O	C	575		575
DTC Acne Campaign	50	1,010	O	0	0	0	0	O			1,060
General Product Support	100	0	o	O	115	o	0	C	215		215
									0		0
									9		<u> </u>
_									0		
M1 Increases	775	1,010	a	0	130	o	O	ā	1,915	Ó	1,915

- Direct To Consumer Campaigns.
- 2 Medical affairs and professional program spending should tie to the spending levels outlined in the Integrated Medical Strategic Plan.
- 3 The Meeting Planning and Career Training & Development departments should provide costs for Launch Meetings and CT&D, respectively.
- 4 The Primary Care or Specialty Care Finance Director should provide the cost per field force presentation used to calculate total field force costs.

C. Revenue Impact of Max Case Investment

	2001	2002	2003	2004	2005
	Year One	Year Two	Year Three	Year Four	Year Five
Total Base Case revenue:	622,000	500,000	410,000	350,000	300,000

Marketing Initiatives	Rationale for Revenue Change Estimate (Revenue Driver Effect, Supporting Data, Analogs)	Max Case Revenue						
Pregnancy Prevention	FDA may require PPP as part of oral isotretinoin labelling, which may serve to delay market entry of a generic competitor. As such, PPP in the label serves to defend Accutane revenues only in the year of the competitive launch (2002)	o	10,000	a	O	0		
NF Conversion	Rapid NF market conversion (i.e. adequate levels of personal selling, professional promotion, publications and C.E.) is essential for preserving future year revenue stream	15,500	3,000	O	O	0		
Physician Prescriber Program	Augments the market conversion to NF (2001-2002) and continues to establish Roche as a leader in dermatology	2,500	2,500	1,076	1,000	1,000		
DTC Acne Campaign	Increased DTC spending serves to drive more untreated patients into the patient pool resulting in a larger patient base for Accutane	6,000	1,725	1,500	1,300	1,300		
General Product Support	Supports key activities to facilitate the conversion of current to new formulation.	17,000	15,775	3,424	1,700	1,700		
	Total revenue change:	41,000	33,000	6.000 ~ -	4,000	4,000		
	Total Max Case revenue:	663,000	533,000	416,000	354,000	304,000		

A. Marketing Initiatives Investment Decrease Summary

Marketing Initiatives	Description of Change and Rationale for Min Level	2001 Investments (Year One)	2002 Investments (Year Two)	2003 Investments (Year Three)
Pregnancy Prevention	PPP is a driver of revenue preservation and NOT revenue expansion	\$757	\$230	\$ 150
NF Conversion	Failure to provide adequate resourcing to convert from current formulation to new formulation rapidly will manifest as a significant reduction in revenues in future years	\$463	\$384	\$325
Physician Prescriber Program	Reducing expenditures in this area serves to counter the rapid conversion to NF and weakens the Roche franchise position as a leader in dermatology	\$647	\$234	\$631
DTC Acne Campaign	Cuts made in earlier years reduces overall treatment seeking patient pool producing the most dramatic effect on the earlier year revenues (2001-2002) when brand exclusivity exists	\$1,300	\$1,700	\$3,785
General Product Support	Cuts made during conversion to new formulation have the most significant effect in the earlier years	\$272	\$355	\$653
		so	\$0	\$0
		\$0	\$0	\$0
		\$0	\$0	\$0
-		\$0	\$0	\$0
	Investment Decrease:	\$3,439	\$2,903	\$5,544

Note:

This summary reflects a Decrease from Base Case, not total Min investments. Please refer to Section 10, Marketing Initiatives Summary Report to see total Min investments and comparisons.

B. Marketing Initiatives Investment Decreases by M1 for Year 2001

Min Case: Decreases from Base Case

Marketing Initiatives	Promotion	DTC:	Prof. Programs	Medical Affairs ²	Product Support	Field Programs	Launch Meeting s ³	CT&D,	SubTotal	Field Force	Initiative Decreases
Pregnancy Prevention	300	0	400	a	57	0	0	0	757		757
NF Conversion	298	o	100	٥	65	O	0	0	463		463
Physician Prescriber Program	397	o	250	0	0	o	O	0	647		647
DTC Acne Campaign	100	1,200	O	O	0	O	O	0			1,300
General Product Support	100	o	0	0	172	O	0	0	272		272
									0		0
									0		0
M1 Decreases	1,195	1,200	750	o	294	o	O	O	3,439	O	3,439

- 1 Direct To Consumer Campaigns.
- 2 Medical affairs and professional program spending should tie to the spending levels outlined in the Integrated Medical Strategic Plan.
- 3 The Meeting Planning and Career Training & Development departments should provide costs for Launch Meetings and CT&D, respectively.
- 4 The Primary Care or Specialty Care Finance Director should provide the cost per field force presentation used to calculate total field force costs.

B. Marketing Initiatives Investment Decreases by M1 for Year 2002

Min Case: Decreases from Base Case

Marketing Initiatives	Promotion	DTC'	Prof. Programs	Medical Affairs ²	Product Support	Field Programs	Launch Meeting s ³	CT&D3	SubTotal	Field Force	Initiative Decreases
Pregnancy Prevention	125	O	100	o	5	0	O	0	230		230
NF Conversion	184	O	200	O	O	0	0	0	384	•	384
Physician Prescriber Program	234	a	O	a	O	O	0	0	234		234
DTC Acne Campaign	200	1,500	0	O	0	0	0	0	1,700	in depth, Cal	1,700
General Product Support	25	o	O	0	330	O	0	0	355		355
									0		0
									0		0
M1 Decreases	768	1,500	300	O	335	o	0	0	2,903	o	2,903

- Direct To Consumer Campaigns.
- 2 Medical affairs and professional program spending should tie to the spending levels outlined in the Integrated Medical Strategic Plan.
- 3 The Meeting Planning and Career Training & Development departments should provide costs for Launch Meetings and CT&D, respectively.
- 4 The Primary Care or Specialty Care Finance Director should provide the cost per field force presentation used to calculate total field force costs.

B. Marketing Initiatives Investment Decreases by M1 for Year 2003

Min Case: Decreases from Base Case

Marketing Initiatives	Promotion	DTC'	Prof. Programs 2	Medical Affairs ²	Product Support	Field Programs	Launch Meeting s ³	CT&D,	SubTotal	Field Force	Initiative Decreases
Pregnancy Prevention	100	a	a	o	50	O	a	0	150		150
NF Conversion	25	O	300	o	0	0	0	0	325	o	325
Physician Prescriber Program	531	ā	100	Q	a	o	O	0	631		631
DTC Acne Campaign	275	3,510	0	o	O	O	0	0	3,785	· .	3,785
General Product Support	50	0	o	0	603	o	0	0	653		653
		j							_ 0		, 0
		3							O	· .	0
									0		0
									O		0
M1 Decreases	981	3,510	400	0	653	o	a	0	5,544	a	5,544

- Direct To Consumer Campaigns.
- 2 Medical affairs and professional program spending should tie to the spending levels outlined in the Integrated Medical Strategic Plan.
- 3 The Meeting Planning and Career Training & Development departments should provide costs for Launch Meetings and CT&D, respectively.
- 4 The Primary Care or Specialty Care Finance Director should provide the cost per field force presentation used to calculate total field force costs.

C. Revenue Impact of Min Case Investment

	2001	2002	2003	2004	2005
	Year One	Year Two	Year Three	Year Four	Year Five
Total Base Case revenue:	622,000	500,000	410,000	350,000	300,000

Marketing Initiatives	Rationale for Revenue Change Estimate (Revenue Driver Effect, Supporting Data, Analogs)	Min Case Revenue						
Pregnancy Prevention	PPP is a driver of revenue preservation and NOT revenue expansion	a	O	0	Q	0		
NF Conversion	Failure to provide adequate resourcing to convert from current formulation to new formulation rapidly will manifest as a significant reduction in revenues in future years	38,000	32,500	18,000	15,000	12,000		
Physician Prescriber Program	Reducing expenditures in this area serves to counter the rapid conversion to NF and weakens the Roche franchise position as a leader in dermatology	7,500	7,500	4,500	4,500	4,000		
DTC Acne Campaign	Cuts made in earlier years reduces overall treatment seeking patient pool producing the most dramatic effect on the earlier year revenues (2001-2002) when brand exclusivity exists	10,000	10,000	3,000	3,000	2,000		
General Product Support	Cuts made during conversion to new formulation have the most significant effect in the earlier years	20,500	19,000	5,500	5,500	5,000		
	Total revenue change:	76,000	69,000	31,000	28,000	23,000		
	Total Min Case revenue:	546,000	431,000	379,000	322,000	277,000		

A. Comparison Report by M1 for Year 1

A. Comparison Report by M1 for Year 2

A. Comparison Report by M1 for Year 3

B. Comparison Report by Marketing Initiatives for Year 1

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B. Comparison Report by Marketing Initiatives for Year 2

B. Comparison Report by Marketing Initiatives for Year 3

11. Alternate Environmental Scenarios

A. Primary Scenario

Total Revenue Implications	2001 (Year One)	2002 (Year Two)	2003 (Year Three)
Min	\$546,000	\$431,000	\$379,000
Base	\$622,000	\$500,000	\$410,000
Max	\$663,000	\$533,000	\$416,000
Total Investment Implications	2001	2002	2003
Min	\$31,458	\$26,758	\$19,764
Base	\$34.897	\$29,661	\$25,308
Max	539,066	\$32,111	\$27.223

- A. Product Data
- Objects/Rich Text/Attachments

B. Product M1 Data

Objects/Rich Text/Attachments



<----- FDA Budget 2000

Other Sheets:



Please note that the M-1 has been revised to include a DTC section, with accompanying categories and detail elements. Please restate your 2000 Budget in this new format for the 2000 LE if you budgeted DTC expenses. If you have not budgeted DTC expenses, leave this section blank and provide changes for the other categories of expenses.



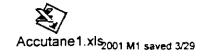
The worksheets above are also provided as attachments below in the event that your computer doesn't have sufficient memory to process the OLE objects. Click on the attachments and detach them to your hard drive. You may then open them in Excel. Keep in mind that while changes made to OLE objects are saved back into NorthStar, attachments are separate copies so any changes can be saved in the worksheet but you must manually put them into NorthStar. If you make changes to the worksheets and you wish those changes to be stored in NorthStar and visible to others, you must re-attached the worksheets after you have saved your changes. To do this, select File > Attach while editing this document. Select the worksheets from your hard drive.



Accutane3.xls_{2000Budget saved 3/29}



Accutane2.xls_{2000LE} saved 3/29



C. Product Strategic Plan Fin'l Summary

• Objects/Rich Text/Attachments



D. Patient Driven Forecast

Objects/Rich Text/Attachments



E. Market Research Plan

Objects/Rich Text/Attachments



G. Infrastructure Resources

Objects/Rich Text/Attachments



Other Resource
Requirements