United States Senate

COMMITTEE ON FINANCE

WASHINGTON, DC 20510-6200

August 12, 2009

Via Electronic Transmission

The Honorable Herb Kohl
Chairman
United States Senate Special Committee on Aging
Washington, DC 20510

Dear Chairman Kohl:

The United States Senate Committee on Finance (Finance) has jurisdiction over the Medicare and Medicaid programs and, accordingly, a responsibility to the more than 100 million Americans who receive coverage under these programs. As Chairman and Ranking Member of the Finance Committee we have a duty to protect the health of all Americans and safeguard taxpayer dollars authorized and appropriated by Congress for health programs.

On August 5, 2009, you sent us a letter requesting documents related to continuing medical education (CME) and other issues regarding the relationship between industry and academia. We are attaching several documents to this letter that are responsive to this request with the understanding that these documents are now public.

Thank you for your attention to this matter and dedication to transparency. If you have any questions, please do not hesitate to contact Christopher Law with Senator Baucus or Paul Thacker with Senator Grassley at (202) 224-4515.

Sincerely,

Max Baucus
Chairman

Charles E. Grassley
Ranking Member

Lexapro Documents

CME Payments
Payments to Professional Societies
Payments for Studies
Payments to Physicians

Lexapro
FY04 Marketing Plan

FOREST LABORATORIES, INC.

FISCAL YEAR 2004 MARKETING PLAN

PRESENTED BY:
John Ameres
Liat Ashkenazi
Steve Closter
Nefertiti Greene
Laura Lavell
John MacPhee
Nikhil Nayak
Frank Preziosi
Renata Reis
Dawn Walters
Matt Warburton
Kelvin Wong
Claire Zinnes

Developed April 1. 2003

EXECUTIVE SUMMARY

Fiscal Year 2004 (FY04) still marks the launch phase for Lexapro™, escitalopram oxalate. This document outlines Forest Laboratories, Inc.'s marketing plan for the continued launch of Lexapro in the U.S. market. This plan covers all aspects of the launch period including a market analysis, objectives, SWOT analysis, critical issues, a detailed description of FY04 strategies and tactics, including the launch of the generalized anxiety disorder (GAD) indication in Q4 FY04.

LEXAPRO DEVELOPMENT

On August 12, 2002 Lexapro received approval from the FDA for the treatment of major depressive disorder. After stocking the trade and training the sales representatives, sales force promotion of Lexapro commenced on September 5, 2002. As of April 1, 2003, Lexapro has 10.4% of the new prescription market share and 7.7% of the total prescription market share. This market share demonstrates the initial success of Lexapro's launch. Lexapro is currently tracking as the sixth best launch in pharmaceutical history with a high likelihood of surpassing Viagra® (sildenafil citrate)[1] and Clarinex® (desloratadine)[2], which began declining after initial spikes in the first 4 months of launch. Although Lexapro has encountered initial success, the aggressive launch phase continues as current and upcoming SRI competitors are increasing their efforts.

Further motivation for the competitive response can be gleaned from the fact that Lexapro's gains in new prescription market share have come at the expense of all competitors, not just Celexa. As of April 1, 2003, 50% of Lexapro's growth has come from Celexa and 50% from the other competitors, primarily the Paxil®[3] (paroxetine hydrochloride) franchise. Since the launch of Lexapro, every SSRI has lost market share and the growth for Effexor® XR (venlafaxine hydrochloride)[4] has slowed down. However, since January of 2003, the competitors are beginning to rebound as Effexor XR has slowly continued its growth, Zoloft® (sertraline hydrochloride)[5] has steadied its declines and even the fluoxetine franchise has stabilized. Furthermore, another Eli Lilly compound, Cymbalta™ (duloxetine hydrochloride)[6], an SNRI used in the treatment of MDD with a potential focus on pain and other somatic symptoms is due to launch in FY04. For all of these reasons, in FY04, Lexapro will need to increase its competitive efforts in order to combat the competitive responses and new competitor entries.

[1] Viagra is a registered trademark of Pfizer Inc.

[2] Clarinex is a registered trademark of Schering Coporation.

[3] Paxil is a registered trademark of GlaxoSmithKline

[4] Effexor XR is a registered trademark of Wyeth-Ayerst Laboratories.

[5] Zoloft is a registered trademark of Pfizer Inc

[6] Cymbalta is a trademark of Eli Lilly and Company.

COMMUNICATION OBJECTIVES

- Communicate the positioning of Lexapro across all promotional venues: "Lexapro, the single isomer of Celexa, is an effective first-line SSRI for all adult depressed patients, which offers superior efficacy and tolerability over all SRIs."
- Incorporate the seven key selling points in every program

PROMOTIONAL OBJECTIVES

- Achieve first place in detail dollar share of voice in the SRI market
- Maintain SRI category leadership in number of journal ad inserts
- Maintain SRI category leadership in total number of medical education events (including CME symposia, speaker programs, teleconferences, and peer selling programs)
- Generate significant Lexapro specific news coverage to both consumers and healthcare professionals
- Have Lexapro included in all depression/anxiety related round up articles/stories that discuss treatment

MANAGED CARE OBJECTIVES

- Gain unrestricted formulary access for Lexapro
- Improve the formulary position of Lexapro in the SSRI class by:
    1) Continue to establish favorable tiered co-pay position for Lexapro versus competitors
    2) Pre launch GAD data initiatives to improve formulary status
    3) Improve existing Lexapro formulary status to more favorable position
    4) Non formulary to formulary
    5) 3rd to 2nd tier
    6) 2nd tier to 1 of 2 preferred
- Exceed individual MCO market share and net sales goals as defined in account manager business plans through enhanced, targeted pull-through efforts.
- Target pull-through efforts and resources
    1) 60% for top tier accounts at or below national market share
    2) 40% to maximize potential and reinforce positive relationships in high performing top tier MCOs

- Increase Lexapro promotional noise level through improved communication to external customers regarding the value of Lexapro in managed care

- Establish baseline managed care training for field force beginning with Phase I training.

  1) Develop ongoing coaching tools for District Manager's to implement on a continous basis with field representatives

- Integrate communication between Managed Healthcare Operations, Lexapro Brand Team, and Field Sales Force

CRITICAL ISSUES

SHARE OF VOICE LEADERSHIP

The antidepressant market is the most heavily detailed category in the pharmaceutical industry. It is therefore imperative that Lexapro maintain SOV leadership in FY04 by:

- **Continue to competitively sell:** Leverage strong comparative and clinical data including head-to-head venlafaxine and sertraline data in MDD and head-to-head paroxetine data in GAD.

- **Maintain/increase field support:** Continue leadership in Lunch & Learns and detailing, and increase samples

- **Increase Med Ed efforts:** More sponsorships of CME, increased level of speaker programs, maintain level of teleconferences and peer selling

- **Expansion contingencies:** Prepare for internal disruptions in the field due to the promotion of other products and potential launches

"OUT PERFORM" IN ALL MARKET SEGMENTS

In order to achieve market dominance, Lexapro cannot lag in any market segments. In FY04, Lexapro will out perform in the following market segments:

- **Disorder (anxiety):** Maximize pre-launch and launch efforts in GAD

- **Provider (psych):** Accelerate psychiatry penetration and make Lexapro the standard of care. Be proactive with selectivity message to address competitors head on

- **Patient Segment (age):** Generate more geriatric and pediatric data and pursue indications as necessary

- **3rd Party Access:** Secure access (formularies and VAs) and pull through (LTC)

INNOCULATION

In an effort to be prepared for the expected and unexpected attacks from competitors and competitive entry, it is necessary to predict and provide responses for such situations. A number of issues effecting Lexapro have been identified. They are:

- **SSRIs versus non-selective reuptake inhibitors (SNRIs, others)**

There has been a trend in the SRI category of promoting reuptake inhibition at more than one receptor site as a benefit to patients in terms of efficacy. Products such as Effexor XR and duloxetine have reuptake inhibition at multiple sites (5HT and NE). Even SSRIs such as Zoloft and Paxil have promoted their more modest effects at the Dopamine and NE receptor sites respectively. The promotional message from these findings has focused on enhanced efficacy versus products that have their primary effects mediated by reuptake blockade at only the serotonin receptor site. Since Lexapro is the most selective SSRI, it could be the subject of criticism relating to this issue.

- **Pending Launch of Cymbalta**

Lilly is poised to launch Cymbalta (duloxetine HCL) an SNRI that will be positioned as a dual action agent from its starting dose and as the "new standard of depression therapy." Lilly is putting focus on the somatic symptoms of pain in their depression trials and may pursue this indication in the future. Currently, Lilly has some manufacturing issues at its Indianapolis plant that has delayed the launch. However, when approved, Cymbalta could be a major threat as Lilly has tremendous resource potential.

- **Generic Paroxetine**

GlaxoSmithKline is currently in litigation with Apotex regarding the patent of Paxil and the availability of a generic paroxetine. There is a strong likelihood that this will not occur until late 2004 or 2005; however, Lexapro must be prepared especially in managed care arenas with the introduction of a second generic to the class.

- **European News**

Although a completely different regulatory environment exists in Europe, news and events there may have an adverse affect on the U.S. market. Labeling language and potential non-approval in certain countries may have a negative effect on Lexapro in the U.S. market.

SUMMARY/CONCLUSION

The FY04 tactical plan contains many field and non-field based programs to continue the successful launch of Lexapro. All tactics are designed to increase promotional share of voice and help Lexapro outperform in all market segments of indications (anxiety), providers (psychiatrists), third-party payers (managed care) and age groups (pediatric and geriatric development programs). The launch of the GAD indication will also assist Lexapro achieve market dominance in years to come. With more data and indications on the way, Lexapro promotion will remain strong throughout the immediate future.

Market Sales[13]

A. TOTAL SALES

Zoloft dominated the SRI market in terms of dollar sales in 2002, while Prozac sales were more than cut in half. Paxil sales were above $2 billion, with Celexa and Effexor close behind at $1.587 billion and $1.524 billion respectively. Being a late entrant into the market in 2002, Lexapro's sales were just shy of $1 million. While the overall market remained constant, all of the SRIs, with the exception of Prozac, Effexor, Remeron, Luvox, Fluvoxatine, and Serzone exhibited double-digit sales growth in 2002.

Table 3.0: SRI Dollar Sales

Product	2001 Total Sales† (billions)	2002 Total Sales† (billions)	Change (%)	Share (%)
SRI Market	$10.695	$10.690	0.0	100
Zoloft	$2.271	$2.545	12.1	23.8
Paxil	$2.154	$2.341	8.7	21.9
Paxil CR	$0	$0.205	N/A	1.9
Celexa	$1.156	$1.587	37.2	14.8
Effexor XR	$1.106	$1.524	37.7	14.3
Fluoxetine	$0.631	$0.749	18.7	7.0
Prozac	$2.074	$0.428	(79.4)	4.0
Remeron	$0.399	$0.388	(2.9)	3.6
Serzone	$0.385	$0.272	(29.4)	2.5
Paxil CR	-0-	$0.205	N/A	1.9
Effexor	$0.137	$0.135	(1.6)	1.3
Remeron Soltab	$0.045	$0.127	182.8	1.2
Prozac Weekly	$0.061	$0.105	72.3	1.0
Sarafem	$0.093	$0.103	10.3	1.0
Lexapro	-0-	$0.099	N/A	0.9
Fluvoxamine	$0.080	$0.062	(22.3)	0.6
Luvox	$0.103	$0.022	(78.4)	0.2
Wellbutrin+SR +generic	$1.201	$1.541	28.4	

† Includes chain store pharmacies, independent pharmacies, food stores, LTC facilities, mail order houses, federal facilities, non-federal hospitals, clinics, and direct purchasing staff HMOs, home health care, misc. channels

[13] Retail and Provider Perspectives ©2002 IMS Health

B. TOTAL PRESCRIPTIONS

Although the overall trends are the same Paxil and Zoloft continue to fare better when it comes to total prescriptions as a result of continuing refills. For the year 2002, Zoloft was the market leader (22.3%), followed by Paxil (20.06%). Celexa demonstrated the second to largest growth amongst all SRIs (33.29%) and secured 15.81% of total prescriptions. While Effexor XR continues to grow, it increased growth at a slower rate of 31% [Table 3.2]. Lexapro's total share of prescriptions for 2002 was .9% and growing.

Table 3.2: SRI Total Prescriptions

Product	2001 TRx (thousands)	2002 TRx (thousands)	Change (%)	Share (%)
Market	121,910	140,072	14.90	100
Zoloft	27,974	31,229	11.64	22.30
Paxil	26,058	28,103	7.85	20.06
Celexa	16,612	22,142	33.29	15.81
Fluoxetine	7,287	21,227	+++	15.15
Effexor XR	11,321	14,885	31.48	10.63
Remeron	5,330	4,877	(8.50)	3.48
Serzone	4,671	3,065	(34.40)	2.19
Prozac	16,875	2,908	(82.77)	2.08
Paxil CR	-0-	2,386	N/A	1.70
Remeron Soltab	634	2,298	+++	1.64
Effexor	1,836	1,778	(3.17)	1.27
Prozac Weekly	705	1,312	86.07	.094
Lexapro	-0-	1,256	N/A	0.90
Sarafem	1,135	1,232	8.53	0.88
Fluvoxamine	916	1,212	32.35	0.87
Luvox	556	162	(70.90)	0.12

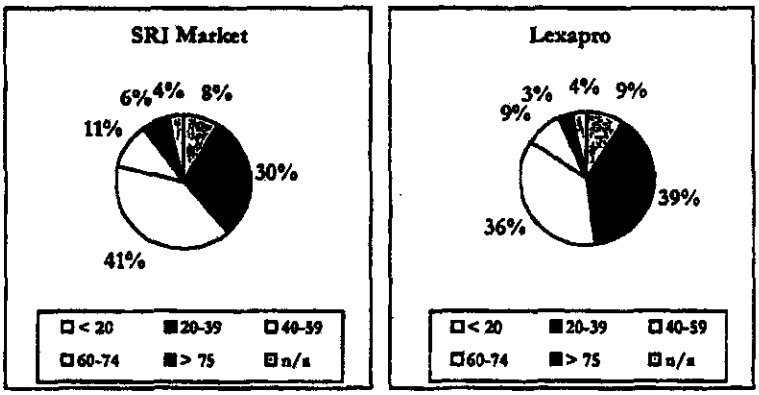
1. REFILL RATES

Increases in the number of new prescriptions, average prescription sizes, and refill rates have fueled growth of the SRI prescription market. Each product in the market posted equal or higher refill rates and prescription sizes in 2002 than 2001 [Figure 3.7]. The average ratio of TRx to NRx was 2.26.

E. USES BY AGE

Depression is an illness that affects all ages and SRIs are used for patients ranging from the very young to the very old. Eight percent of total SRI usage is for patients under the age of 20 (this age group represents 29% of the U.S. population.) SRI usage is most prevalent in the adult population. Patients between the ages of 20-39 and 40-59 represent the majority of the market at 30% and 41% of usage, respectively. Usage of SRIs in older patients (over 60 years of age) mirrors the general population at 16% [Figure 3.10].

Figure 3.10: CY 2002 Usage by Age: SRIs vs. Lexapro



Product market shares vary by age group, with Lexapro under performing in the under 20 age segment (9%). This is expected since it is a relatively new product with which physicians are not as comfortable with the SSRIs in treating children.

Despite their product profile, which makes them an ideal product for the elderly, Celexa and Lexapro do not significantly over perform in this segment. Zoloft and Paxil/CR both have a higher percentage of reported uses in the elderly population, both in patients 60-74 and >75.[Table 3.5].

Table 3.5 CY 2002 SRI Usage by Age (Columns Total to 100%)

Product	All Ages (%)	<20 (%)	20-39 (%)	40-59 (%)	60-74 (%)	>75 (%)	Unspecified (%)
Market	100.0	8.5	30.1	40.2	11.2	6.4	3.6
Lexapro	3.1	3.4	4.0	2.8	2.5	1.6	3.2
Celexa	17.4	16.0	17.9	16.4	17.7	21.5	18.0
Effexor+XR	13.8	11.3	13.8	16.2	9.4	9.2	13.8
Luvox	1.2	2.7	1.1	1.2	1.2	.07	0.4
Paxil+CR	21.0	22.3	22.1	18.8	22.7	24.4	20.9
Prozac (brand+ generic)	15.8	14.3	15.8	17.7	15.0	7.2	16.5
Remeron Line	4.5	3.0	2.9	4.8	6.2	10.5	3.1
Sarafem	0.8	0.3	1.4	0.6	0.1	0.0	1.5
Serzone	2.4	1.0	1.8	3.4	2.4	0.8	2.9
Zoloft	20.0	25.6	19.1	18.0	22.9	24.1	19.7

Paxil maintained the positions it achieved in 2001 showing movement only in the 20-39 age group (+3%) and the 40-59 (-2%) age groups. Zoloft showed significant movement only in the 40-59 group (+1%) and maintained (moving only ± 1%) in the other age groups. Lexapro's data cannot be compared to 2001, but it has the majority of its patient population rooted in the 20-39 and 40-59 age group, while Celexa's share remained constant across all age groups (± 2%). Effexor XR was relatively constant in all age groups showing significant movement in the 60-74 age group (-3%).

F. PRESCRIPTIONS BY SPECIALTY

Primary care physicians (PCPs) write 30.3% of all SRI NRx and psychiatrists account for another 31.1%. Together, these two specialties prescribe almost eight out of ten SRI NRx with PCPs steadily becoming a large portion. OBGs (3.6%) and neurologists (1.5%) fall well behind in terms of prescribing potential.

Celexa till has good penetration with the specialist although the gap is narrowing and although Lexapro's numbers were not huge for the end of 2002 they are steadily growing [Table 3.6]. Paxil/CR, Zoloft, and Effexor/XR also all over performs with psychiatrists – having a greater share than Celexa and Lexapro – and slightly under performs with PCPs and OBGs. Prozac and generic fluoxetine both have a higher than average share in the OBG office especially since the launch of Sarafem and its PMDD indication. .

It should be noted that NRx market share for Celexa (Table 3.6a) indicates that Celexa has an even distribution among all specialties and hovers around 14% in all categories.

e) Lexapro Oral Solution

Lexapro oral liquid was launched in late 2002. The Lexapro oral liquid is peppermint-flavored and is concentrated as a 5 mg/5mL solution. It is currently packaged in 240 mL (8 oz) bottles which deliver approximately twenty-four 10mg doses per bottle.

Lexapro oral liquid has not been aggressively promoted to physicians and has never been sampled.

Table 3.17: SSRI Oral Liquid New Prescriptions

Product	2001 NRx (thousands)	2002 NRx (thousands)	Change (%)	Share (%)
Market	166	172	3.6	100.0
Fluoxetine	16	56	+++	32.6
Paxil	53	46	(13.2)	26.7
Celexa	19	31	63.2	18.0
Zoloft	12	20	66.7	11.6
Prozac	66	19	(71.2)	11.0

VI. SRI MARKET PROMOTION[18,19,20,21,22,23]

A. DETAILING

The SRI market is a highly competitive one, with 4.5 million physician contacts recorded in calendar year 2002. This was achieved through several of the largest sales forces in the pharmaceutical industry [Figure 3.18]. Both Paxil and Prozac Weekly increased their sales forces, 18% and 15%, respectively. Remeron *decreased* their sales force by 53%.

[18] Integrated Promotional Services Audit ©2002 IMS Health.

[19] National Journal Audit ©2002 IMS Health.

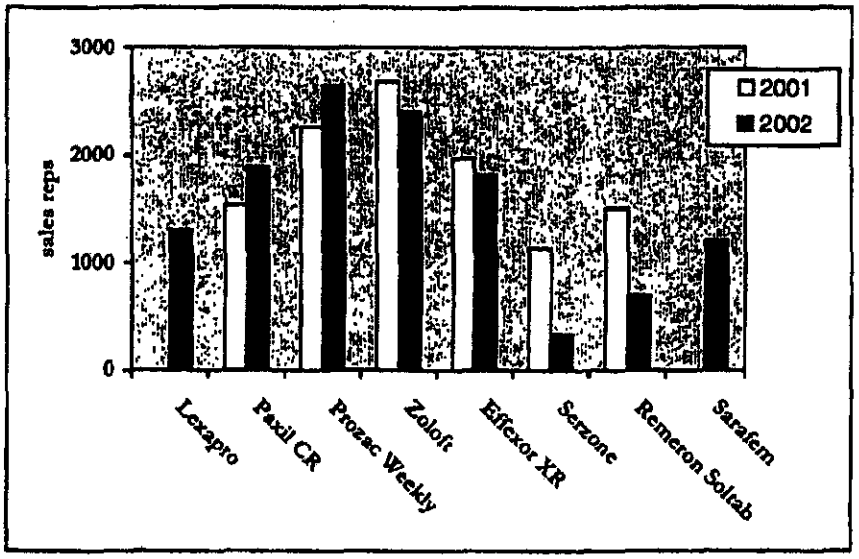
[20] Promotional Meeting and Event Audit ©2002 Scott-Levin Associates.

[21] NPA Plus ©2002 IMS Health.

[22] Drug Topics® Red Book® ©2002 Medical Economics Company, Inc.

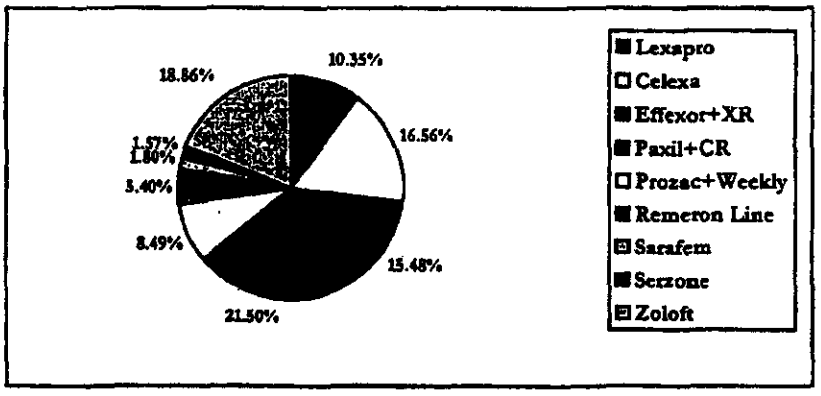
[23] Spring 2002 LTC Promotional Audit ©2002 Scott-Levin Associates.

Figure 3.18: SRI Sales Force Size



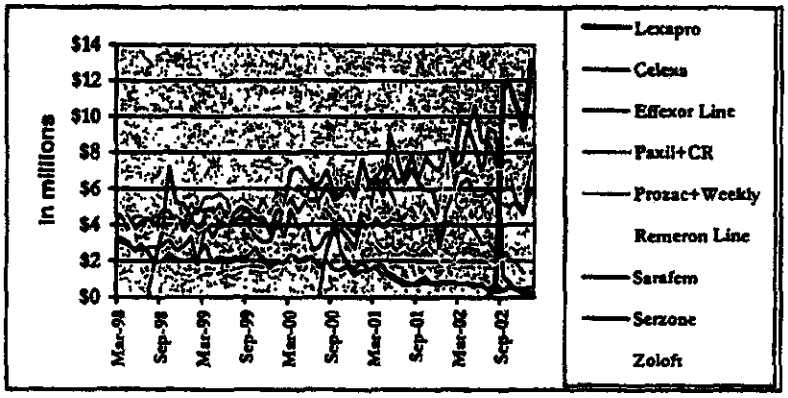
IMS audits reported Lexapro to have 374,000 detailing contacts in 2002 while Celexa had 611,000. Zoloft was the market leader in this category with a little over 1 million detailing contacts. Paxil/CR and Effexor XR and were second and third behind Zoloft with 983,000 and 653,000 detailing contacts, respectively.

Figure 3.19: CY 2002 SRI Detailing Dollars



Detailing expenditures have increased steadily and significantly for Paxil, Celexa and Effexor XR while Serzone, Sarafem, Prozac and Prozac Weekly, and Zoloft have all reduced their spending during 2002. [Figure 3.20].

Figure 3.20: SRI Detailing Dollars Over Time



1. DETAILING BY SPECIALTY

All of the SRIs spend more detailing time overall in PCP offices, given the large size of this audience. The bulk of SRI detailing time is spent on PCPs (50.9%) and PSYCHs (34.1%), with OBGs (6.9%) and Neurologists (1.8%) falling far behind in detailing emphasis [Table 3.8]. This distribution of promotional effort is proportional to the contribution each specialty makes to total SRI volume.

Table 3.8: CY 2002 SRI Detailing Dollars by Specialty (Columns Total to 100%)

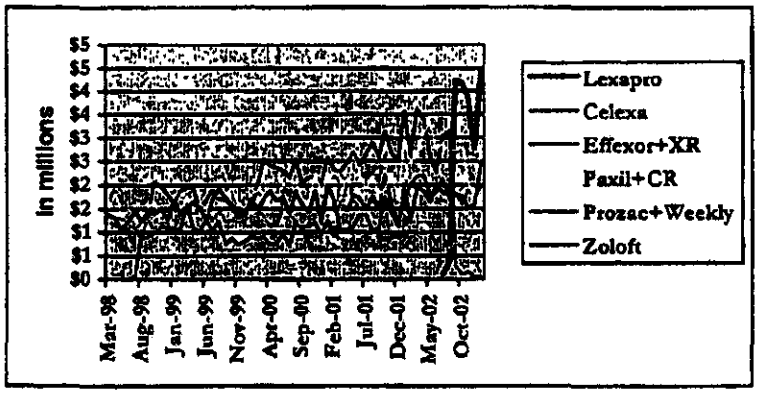
Product	All Specialties (%)	PCP (%)	PSY (%)	OBG (%)	N (%)	All Others (%)
Lexapro	10.4	10.5	10.6	8.3	9.9	10.2
Celexa	16.6	16.9	17.0	12.6	15.2	15.7
Effexor+XR	15.5	16.4	15.5	11.1	9.4	13.9
Paxil+CR	21.5	22.3	22.0	11.5	25.3	22.1
Prozac+Weekly	8.5	10.1	6.6	6.8	5.1	8.6
Remeron Line	5.4	3.7	9.8	0.1	1.2	2.7
Sarafem	1.8	1.1	0.1	16.5	0.0	0.8
Serzone	1.6	0.4	3.8	0.0	1.9	0.3
Zoloft	18.9	18.6	14.3	33.2	32.0	25.6

Table 3.8 (a): CY 2002 SRI Detailing Dollars by Specialty (Rows total 100%)

Product	PCP (%)	PSY (%)	OBG (%)	N (%)	All Others (%)
SRI Market	50.9	34.1	6.9	1.8	6.4
Lexapro	51.5	35.0	5.6	1.7	6.2
Celexa	52.0	35.1	5.3	1.6	6.0
Effexor+XR	54.0	34.2	5.0	1.1	5.7
Paxil+CR	52.8	35.0	3.7	2.1	6.5
Prozac+Weekly	60.3	26.7	5.6	1.1	6.5
Remeron Line	34.5	61.8	0.1	0.4	3.1
Sarafem	31.5	1.9	63.7	0.0	2.9
Serzone	13.0	83.6	0.0	2.1	1.3
Zoloft	50.3	25.9	12.2	3.0	8.6

In many ways, SRI performance with each specialty mirrors the promotional effort devoted to that segment. In the OBG offices, Zoloft and Prozac have a greater share of voice and a correspondingly higher market share. Effexor XR appears to have broadened its promotion to hit PCPs more. Its share of voice with PCPs is now significantly higher than its share of voice with psychiatrists. Lexapro and Celexa detailing by specialty is relatively similar with slightly higher share of voice with psychiatrists and PCPs and slightly lower with OBGs. Meanwhile Paxil has its highest share of voice with neurologists and it's lowest with OBGs.

Figure 3.21: SRI Detailing Dollars by Specialty (Psych)



B. SAMPLING

Total extended unit samples were 408.1 million as of MAT August, 2002 which is down 1.9% from 2001. [Table 3.9]. The sampling trend is a bit different than it was in 2001 when the majority of products increased their sampling. In fact, in 2002, Paxil and Paxil CR, Prozac and Prozac Weekly, Celexa, the Remeron line, Serzone and Luvox all decreased their sampling efforts. The share of Celexa samples in 2002 was 12.7%, up only slightly from 2001, and Lexapro was at 7.9% at the end of 2002. A total of 51.7 million Celexa tablets were distributed in 2002 compared to 58.9 million in 2001 (down 12%) and a total of 34 million Lexapro tablets were distributed in 2002. Celexa and Lexapro's sampling efforts were surpassed by Paxil/CR (88.1 million tablets) and Zoloft (118.5 million tablets) wich showed the most growth in 2002 (up 19%). Celexa and Lexapo were also surpassed by Effexor/XR (72.8 million tablets) which was up 10% from 2001.(Note that the tablet/capsule figures are audited and therefore may be understated by as much as 50%. However, audits are useful in determining relative levels of sampling.)

Table 3.9: CY 2002 SRI Sampling

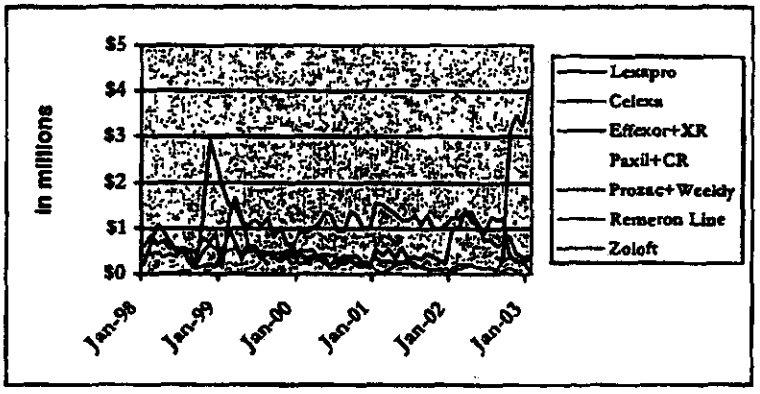
Product	Tabs/Caps Sampled 2001 (millions)	Tabs/Caps Sampled 2002 (millions)	Change (%)	Share (%)
SRI Market	416.2	408.1	(2.0)	100.0
Zoloft	95.9	118.5	23.5	29.0
Paxil+CR	94.5	88.1	(6.8)	21.6
Effexor+XR	65.5	72.8	11.1	17.8
Celexa	58.9	51.7	(12.2)	12.7
Lexapro	-0-	32.4	NC	7.9
Prozac+Weekly	42.2	14.1	(66.5)	3.5
Remeron Line	15.5	13.3	(14.1)	3.3
Sarafem	14.0	9.0	(35.7)	2.2
Serzone	27.6	8.1	(70.8)	2.0
Luvox	2.2	0.1	(95.4)	0.0

Table 3.10: CY 2002 SRI Journal Spend

Product	2001 Journal Spend (millions)	2002 Journal Spend (millions)	Change (%)	Share (%)
SRI Market	$28.59	$39.25	37.3	100.00
Celexa	$14.92	$11.87	(20.5)	30.2
Lexapro	$-0-	$10.45	N/A	26.6
Effexor+XR	$4.84	$10.25	111.8	26.1
Paxil+CR	$2.01	$2.63	31.3	6.7
Zoloft	$2.59	$2.39	(7.7)	6.1
Remeron Line	$2.46	$1.61	(34.5)	4.1
Prozac+Weekly	$1.75	$0.05	(97.1)	0.1
Sarafem	$0.02	$0.00	(100.0)	0.0

Through the twelve months ending December 2002, Celexa was the SRI market leader in journal advertising spend, with a total of $15.237 million [Table 3.10]. This placed Celexa third in the entire pharmaceutical market in terms of journal advertising. In the SRI Market, Lexapro was second in journal advertising with $10.45 million [Table 3.10].

Figure 3.29: SRI Journal Spend

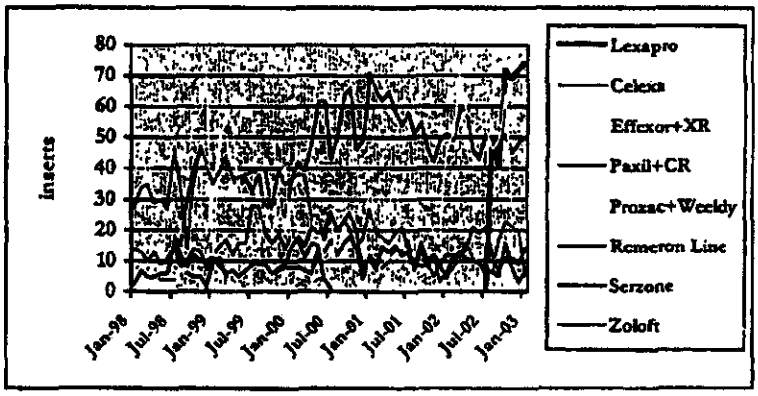


The dollars spent by Celexa remained relatively constant for most of 2002, with a dip in the latter portion of the year [Figure 3.29], and as well, the number of inserts decreased (11%) [Table 3.11]. Lexapro was third amongst SRIs in journal ad inserts with 303 for 2002 [Table 3.11] and their dollars spent was the highest at year end 2002 [Figure 3.29].

Table 3.11: SRI Journal Inserts

Product	2001 Journal Inserts	2002 Journal Inserts	Change (%)	Share (%)
SRI Market	1,539	1,930	25.4	100.0
Effexor+XR	310	602	94.2	21.2
Celexa	676	599	(11.4)	31.0
Lexapro	-0-	303	NA	15.7
Paxil+CR	133	160	20.3	8.3
Zoloft	175	157	(10.3)	8.1
Remeron Line	135	106	(21.5)	5.5
Prozac+Weekly	108	3	(97.2)	0.2

Figure 3.30: SRI Journal Inserts



D. PHYSICIAN MEETINGS AND EVENTS

Physician meetings and events are a crucial element of the marketing mix for any SRI. During 2002, Celexa dominated the market with 9,069 events that reached approximately 60,000 physicians. Lexapro was a close second with 7,700 events in 2002 reaching approximately 47,000 physicians[Table 3.12] [Figure 3.31]. The audited cost for these events was $39.5 million for Celexa which was a 9% decrease from 2001 whereas Lexapro spent $31.4 million and was third in the category [Table 3.13]. While Effexor increased their spend significantly in this category (32%), making them second amongst SRIs. While Prozac and Prozac Weekly significantly reduced their spend (-49%), the number of events diminished at almost the same rate (-35%) . In terms of physician meetings and events in 2002, Celexa was the leader followed by Lexapro, Effexor/XR and Zoloft.

Table 3.12: SRI Physician Meetings and Events

Product	2001 Events	2002 Events	Change (%)	Share (%)
SRI Market	26,695	33164	24.2	100.00
Celexa	7,996	9,069	13.4	27.3
Lexapro	113	7,700	+++	23.2
Effexor+XR	4,484	6,391	42.5	19.3
Zoloft	2,699	3,411	26.4	10.3
Paxil+CR	4,237	2,895	(31.7)	8.7
Prozac+Weekly	3,602	2,321	(35.6)	7.0
Remeron+Soltab	1,366	618	(54.8)	1.9
Serzone	837	270	(67.7)	0.8
Sarafem	1,349	224	(83.4)	0.7
Duloxetine	12	136	+++	0.4
Cymbalta	-0-	124	NC	0.4
Luvox	-0-	5	NC	0.0

CRITICAL ISSUES

I. SHARE OF VOICE LEADERSHIP

The antidepressant market is the most heavily detailed category in the pharmaceutical industry. It is therefore imperative that Lexapro maintain SOV leadership in FY04 by:

- **Continue to competitively sell:** Leverage strong comparative and switch clinical data including venlafaxine and sertraline (comparative data) and fluoxetine (switch data)
- **Maintain/increase field support:** Continue leadership in Lunch & Learns and detailing, and increase samples
- **Increase Med Ed efforts:** More sponsorships of CME, increased level of speaker programs, maintain level of teleconferences and peer selling
- **Expansion contingencies:** Prepare for internal disruptions in the field due to the promotion of other products and potential launches

II. "OUT PERFROM" IN ALL MARKET SEGMENTS

In order to achieve market dominance, Lexapro cannot lag in any market segments. In FY04, Lexapro will out perform index in the following market segments:

- **Disorder (anxiety):** Maximize pre-launch and launch efforts in GAD
- **Provider (psych):** Accelerate psychiatry penetration and make Lexapro the standard of care. Be proactive with selectivity message to address competitors head on
- **Patient Segment (age):** Generate more geriatric and pediatric data and pursue indications as necessary
- **3rd Party Access:** Secure access (formularies and VAs) and pull through (LTC)

III. INNOCULATION

In an effort to be prepared for the expected and unexpected attacks from competitors and competitive entry, it is necessary to predict and provide responses for such situations. A number of issues effecting Lexapro have been identified. They are:

3) significantly improves depression for many patients beginning at week 1 or 2 (effect may take 4 to 6 weeks)

4) effectively treats anxiety symptoms associated with depression

5) at 10 mg, overall incidence of side effects and drop out rates due to AEs no different than placebo

6) favorable drug interaction profile

7) simple 10 mg starting dose for all patients

IV. PROMOTIONAL OBJECTIVES

- Achieve first or second place in detail dollar share of voice in the SRI market
- Maintain SRI category leadership in number of journal ad inserts
- Maintain SRI category leadership in total number of medical education events (including CME symposia, speaker programs, teleconferences, and peer selling programs)
- Generate significant Lexapro specific news coverage to both consumers and healthcare professionals
- Have Lexapro included in all depression/anxiety related round up articles/stories that discuss treatment

V. MANAGED CARE OBJECTIVES

1) Gain unrestricted formulary access for Lexapro

2) Improve the formulary position of Lexapro in the SSRI class by:

   - Continue to establish favorable tiered co-pay position for Lexapro versus competitors
   - Pre launch GAD data initiatives to improve formulary status
   - Improve existing Lexapro formulary status to more favorable position
   - Non formulary to formulary
   - 3rd to 2nd tier
   - 2nd tier to 1 of 2 preferred

MARKETING TACTICS

I. FIELD SAMPLES

Samples will be packaged in two forms: field samples and patient starter kits. A total of 300 MM 10 mg sample tablets will be produced in FY04. Representatives will not receive samples of the Lexapro 20 mg tablet.

A. FIELD SAMPLES

Lexapro field samples will be provided in individual boxes holding one blister card of seven 10 mg tablets (1x7) in a gravity-feed dispenser holding eight of the 1 x 7 boxes.

60% of all samples or 180 MM tablets produced will be distributed as field samples in FY04.

Timing: Q1 – Q4
Quantity: 180 MM tablets, 25.7 MM starters (1x7 boxes)

B. PATIENT STARTER KITS

Patient Starter Kits (PSKs) which contain two weeks of Lexapro samples along with an educational, branded Lexapro brochure will be sampled to physicians during FY04. The rationale for providing PSKs is twofold. First, many physicians and Managed Care Organizations (MCOs) have been asking for patient education, which is incorporated in a sample. In fact, many physicians have stated that they prescribe Paxil, Zoloft, or Effexor XR because of the PSKs available for those brands. Because physicians are requesting PSKs, their availability will help representatives gain selling time and increase rapport with key physicians.

Second, providing patient education to patients could increase the likelihood that a patient will fill a prescription for Lexapro and become a loyal user. A patient who understands what to expect from Lexapro treatment will be more likely to stay on Lexapro over the long term. The educational brochure in the PSK will be updated to reflect GAD information when appropriate

NOTE: Each PSK will contain fourteen 10 mg tablets of Lexapro along with an educational brochure. Each PSK is in a tri-fold design with six PSKs comprising a sample unit. 40% of samples will be in the form of PSKs equaling over 120 MM tablets or 1.4 MM sample units.

Timing: Q1 – Q4
Quantity: 120 MM tablets, 8.6 MM starters (14 tablets)

Total Estimated Cost: $15,741,464

Bylined Articles
Bylined articles will allow us to fold Lexapro messages into articles on depression, anxiety and co-morbidity developed by (or ghostwritten for) thought leaders. We will identify a Lexapro thoughtleader to place 2-3 bylined articles in trade journals, consumer publications and on the Internet. Estimated costs include article development, revisions and honoraria for the authors. Examples of topics include co-morbidity of depression and anxiety and selectivity.

Timing: Q1-Q4
Estimated Cost: $100,000

Paid Media Outreach
In addition to the traditional editorial media outreach, there are also opportunities in which we can increase control over the final product by paying for the placement. These opportunities, which will supplement our core activities, may include Lexapro message placement in radio programs (e.g., American Health Radio) or other "advertorial" venues. Expenses may include spokesperson honoraria, production costs, logistics and script writing.

Timing: Q1-Q4
Estimated Cost: $200,000

VII. ADVERTISING AGENCY FEES

The advertising agency of record will work on a variety of projects supporting Lexapro during FY04. Most of the projects captured in this tactical plan are listed below. Advertising agency account time is captured in General and Administrative (G&A) fees. All creative and Out of Pockets (OOPs) are captured in individual projects. The list of projects the agency will work on include (more projects may be initiated once identified and finalized):

Annotated Package Insert	Annotated Master Visual Aid	Dosing Card
Annotated Reprints	Clinical Series and Letterhead	Rep Triggered Mail
Patient Education Brochures	Starter Kit Brochure	GAD announcement Mailer
Market Research	Convention Panels	Sales Resource Binder/POA Guide
8 Page Ad	4 Page Ad	2 Page Ad
Hospital Panels	File Card	Master Visual Aid
File Card		

B. VA/DOD SPONSORSHIP FUNDS

Funds have been allocated to the Government Sales Group to increase VA/DoD formulary penetration, enhance formulary position by moving to preferred status, and facilitate pull-through at all VA/DoD hospitals through individualized programs including, but not limited to:

- Local Special Events
- Local Educational Programs
- Pull-Through Programs designed to drive Lexapro NRx and enhance compliance/length of therapy

Funding allocations will be dependent upon submission/approval of well-developed business rationale. A committee composed of members of the Lexapro Brand Team, and Managed Health Care Operations will review all requests.

Timing: Q1 – Q4
Estimated Cost: $250,000 Sponsorship Funds

XI. CONTINUING MEDICAL EDUCATION

The general goal and purpose of the CME program is to: Sponsor the development of continuing medical education activities that will educate physicians and other healthcare providers and assist them in acquiring the most current knowledge in the diagnosis and treatment of depression and other related disorders.

A. ENDURING CME

In order to amortize the content from Forest sponsored symposia at academic conventions and regional programs, Forest will sponsor the development of several enduring CME pieces.

Forest will sponsor "special reports" and "brief communicators" in publications like *CNS News*, *Psych Times*, and the *Journal of Clinical Psychiatry*, as well as university-affiliated newsletters such as Duke University. Four of these 6-8 page CME accredited reports will summarize symposia at ADAA, APA, AAFP, and AAGP. Others will be created to educate physicians on the latest information available on antidepressant treatment.

Timing: Q1 – Q4
Quantity: 6
Cost Per Unit: $100,000
Estimated Cost: $600,000

A reporter from publications like *CNS News*, *Psych Times*, and the *Journal of Clinical Psychiatry* will be sent to cover key Lexapro data presented at important medical meetings. Data from ADAA, APA, ACNP, and WCP will be reported in the journal as a CME supplement.

Timing: Q1 – Q4

Quantity: 4
Cost Per Unit: $75,000
Estimated Cost: $300,000

A videotaped satellite program will be sponsored to extend the reach of our medical education activities into the larger psychiatric community. The content will consist of a videotaped satellite CME broadcast of thought leaders discussing new treatments for depression, anxiety and related disorders.

Timing: Q3
Quantity: 12,000
Cost Per Unit: $8.30
Estimated Cost: $100,000

Total Estimated Cost: $1,000,000

B. INTERNET/ELECTRONIC CME

Online CME

Many physicians now use the Internet as a way to gain CME credits. Sponsoring online enduring CME programs is an effective way of amortizing the high cost of a live program and extending the reach of the program. Symposia sponsored at APA, ADAA, AAFP and AAGP will be placed on the Internet in FY04. Avenue-E/IntraMed will create an online webcast that will reach the audience from the two largest internet sites, E-medicine and MedScape. These CME webcasts will be available within 4-6 weeks of the live program.

Some physicians prefer the interactive format of CD ROMs as their vehicle to gain CME credits. In FY04, Forest will sponsor a CME CD ROM for this audience.

Timing: Q1 – Q4
Quantity: 5
Cost Per Unit: $120,000. - Online CME, $200,000ea. – CD ROM
Estimated Cost: $800,000

C. NATIONAL CME SYMPOSIA

Sponsoring symposia at major meetings will allow thought leaders to present new data as it becomes available as well as address questions from their peers and attending media. Symposia will be sponsored to address key topics of interest for the medical field. The audience at the majority of the meetings will be psychiatrists and PCPs; however, there will also be meetings with OB/GYNs, managed care and others.

The detailed Lexapro symposia plan is provided as part of the Professional Meeting and Symposia appendix to this marketing plan (see *Appendix IV*).

Timing: Q1 – Q4
Quantity: 18
Cost Per Unit: ~$167,000 each
Estimated Cost: $3,000,000

D. REGIONAL CME SYMPOSIA

Forest will continue to sponsor the central development and regional implementation of a series of educational programs to serve multiple medical subspecialties, including primary care and psychiatry. In conjunction with medical education agencies, academic health centers, medical associations and professional societies, Forest will address educational needs that are relevant, problem-based and timely. Approximately 100-200 physicians will be in attendance at each CME regional program.

A series of 80 regional programs will be run by CME Inc. CME Inc. asked Forest for an unrestricted educational grant to sponsor a series regarding anxiety. Dr. Murray Stein, Dr Mark Pollack and others will serve as the Chairmen for this series. There are also potential opportunities with Duke University and Stephen Stahl to conduct regional series on selectivity and preclinical items for psychiatrists.

Timing: Q1 – Q4
Quantity: 145 programs. 110 Psych, 35 PCP
Cost Per Unit: ~$42,000 each
Estimated Cost: $6,000,000

E. SPONSORSHIP OF SCIENTIFIC SESSIONS

Some of the smaller, more prestigious meetings do not accept industry-supported symposia. In such cases, sponsorship of a study group or plenary session is recommended. Marketing will work with the professional relations group regarding potential opportunities. SOBP, NCDEU, ACNP and AAFP are the four meetings that will be targeted in FY04.

Timing: Q1 - Q4
Quantity: 4 events
Cost: $200,000

XII. ADVISOR RELATIONS

A. ADVISOR COMMUNIQUÉS

Forest will communicate regularly with thought leaders, advisors, and Lexapro investigators throughout FY04 to keep them abreast of all pertinent information with Lexapro. Monthly mailings will be developed to transmit information that will include topics like the approval of Lexapro for GAD, the filing of Panic Disorder, posters presented at important medical meetings like ADAA, APA, and ACNP, and recently published data

The detailed Advisor Communiqués plan is provided as an appendix to this marketing plan (see *Appendix XI*).

Timing: Q1 - Q4
Cost: $50,000

B. CONSULTANTS

During FY04, Forest will employ the consultant services of several thought leaders as advisors to Lexapro in order to obtain critical feedback and recommendations on educational and promotional strategies and tactics. Advisors will be selected based upon their specific area of expertise and the marketing and/or medical need(s) at the time.

Timing:	Q1 – Q4
Cost/Hour:	$250
Estimated Cost:	$180,000

C. CONSULTANTS MEETING

A two-day meeting for key escitalopram consultants and thought leaders will be held one year after launch. The purpose of this meeting will be to provide an update to our consultants on the progress of Lexapro and seek advice on the upcoming GAD launch. Half was paid in FY03 for space reservation, recruitment, etc. The remainder will be paid in FY04.

Timing:	Q2
Cost:	$200,000

D. EXECUTIVE ADVISORY BOARDS

The primary purpose of the Lexapro Executive Advisory Board is to gain the counsel of the key opinion leaders from around the country. Ancillary to gaining advice and guidance, the executive advisory board keeps our advisors apprised of the commercial development and potential benefits of escitalopram. Market issues and their potential impact on escitalopram, emerging clinical and preclinical Lexapro data are also discussed. Two one-day meetings in San Francisco & New York are proposed for FY04.

Timing:	Q1-Q4
Quantity:	2
Cost per meeting:	$105,000
Cost:	$210,000

E. PRIMARY CARE ADVISORY BOARDS

The objective of the primary care executive advisory board meetings is to obtain critical feedback and recommendations on educational and promotional strategies and tactics, as well as cultivate, build, and maintain professional alliances with key internists and primary care thought-leaders. The primary care advisory board will consist of nationally recognized internists and PCPs.

The agenda of these meetings will cover an update on the status of Lexapro clinical trials and clinical development plan, and a discussion of marketing strategies to primary care physicians based on the outcomes to date.

Timing:	Q2-Q3
Quantity:	1
Cost per meeting:	$100,000
Cost:	$100,000

discussion on marketing related topics they deem important to their markets. A total of 200 local advisory boards will be conducted in FY04.

Approximately 40 speakers participate as moderators/presenters for the Lexapro local advisory board program. These speakers will be brought together for a training and feedback session on the program. This would allow us to train them on the most current data, including GAD, and address any issues with the program.

Timing:	Q1 – Q4
Quantity:	200
Cost Per Unit:	$28,000
Estimated Cost:	$5,600,000

B. REP PROMOTIONAL PROGRAMS

Through the approximately 2,000 psychiatrists and PCPs that have been recruited and trained to serve as faculty for the Lexapro Speakers' Bureau Program, reps will organize speaker events. These meetings may be large-scale dinner programs with a slide presentation, small roundtable discussions or one on one advocate lunches. The trained psychiatrists and PCPs include national and local thought leaders.

These meetings are necessary to maintain the strong presence and share of voice of Lexapro. In addition, dinner programs provide an opportunity for the rep to interact and build relationships with a number of physicians in their territory.

Timing:	Q1 – Q4
Quantity:	15,000 (1,942 reps, avg. 7.7 per rep)
Cost Per Unit:	$2,300
Estimated Cost:	$34,700,000

C. SPEAKERS' BUREAU ADMIN FEE

The agency will provide all logistical support for the Lexapro Speakers' Bureau. Activities covered may include processing of speaker honorarium, travel and expenses, RSVP management, invitations/posters, and setting up a venue for the program.

The agency's fee is based on the level of their involvement in the planning of the program. The different levels are summarized below:

Allocation 1 - Agency involvement includes securing a speaker and processing honorarium/expenses for the speaker and providing invitations and posters to the rep for distribution.

Allocation 2 - Agency involvement includes securing a speaker, and processing honorarium/expenses for the speaker and coordinating all travel arrangements. Agency will also provide invitations and posters to the rep for distribution.

Allocation 3 - Agency involvement includes full event planning – securing a speaker, developing invitations and posters, managing RSVPs, all logistical arrangements (venue and menu selection, AV needs) and processing honorarium/expenses.

Timing: Q1 – Q4
Quantity: 15,000
Cost Per Unit: $300, 650 or 1,500
Estimated Cost: $4,280,000

D. SPEAKERS' BUREAU SLIDE KIT

A speaker's slide kit containing a comprehensive review of Lexapro data has been developed. The slide kit will be updated as new data, including GAD when approved, becomes available. Speakers at promotional events such as dinner programs, roundtables, grand rounds and other events will use the slide kit.

Timing: Q1 – Q4
Quantity: 2000
Estimated Cost: $400,000

E. SPEAKER TRAINING

Three speaker training meetings will take place during October – December 2003. The meetings will be located in New York, Florida and Los Angeles. 1,000 existing speakers from the speaker's bureau will be recruited and trained on new Lexapro data including GAD. The trained psychiatrists include national and local thought leaders.

Webcast/CD based speaker training will be rolled out in FY04 as well. Divisional Managers will have the opportunity to train additional Lexapro speakers. This program or one similar may be used to update existing speakers who cannot attend a live speaker training meeting on new data.

Timing: Q1-Q4
Quantity: 3
Cost Per Meeting: $800,000
Estimated Cost: $3,300,000

F. SPEAKERS BUREAU ON-LINE COMPONENT

Communication and training of thought leaders and speakers can be optimized by offering them an online resource to alleviate the burden of:

- Disseminating new data
- Training
- Provide current materials

A small secure site will be built for these physicians. Potential site features will include:

- Promotional guidelines
- Slide decks and slide deck updates
- Relevant literature and literature updates
- Press releases
- Travel expenses
- Contact list for Forest

Timing: Q1 – Q4
Estimated Cost: $300,000

XV. LUNCH AND LEARNS

Providing lunch for a physician creates an extended amount of selling time for representatives. It also gives them the opportunity to utilize other selling tools like the lunch and learn video, teleconferences, etc.

Timing:	Q1 – Q4
Quantity:	1,942 sales reps
Cost Per Rep:	$18,500/rep/ year
Estimated Cost:	$36,000,000

XVI. FIELD AIDS

Field aids provide support to the field force to help drive Lexapro prescriptions. In FY04, the sales force will be armed with strong clinical and promotional support for Lexapro. These materials will provide vehicles for rep utilization that will generate interest and help the rep engage the physician in a consultative discussion.

The Lexapro marketing team will provide new selling materials each POA to prevent rep fatigue. In addition, product and category updates will be delivered for reps to keep physician calls relevant and engaging.

A. CLINICAL REPRINTS/POSTERS

The following reprints will be made available in FY04:

1. Gorman J. et al. Efficacy comparison of escitalopram and citalopram in the treatment of Major Depressive Disorder: Pooled Analysis of Placebo-Controlled Trials. *CNS Spectrums.* 2002;

Purpose: To compare the efficacy of escitalopram 10-20 mg vs citalopram 20-40 mg.

2. Burke, W. et al. Fixed dose trial of the single isomer SSRI escitalopram in depressed outpatients. *Journal of Clinical Psychiatry.* 2002; .

Purpose: Compare the efficacy and tolerability of escitalopram and citalopram in the treatment of Major Depressive Disorder.

3. Wade, A. et al. Escitalopram 10 mg/day is effective and well tolerated in the treatment of depression in primary care. *International Clinical Psychopharmacology. 2002*

Purpose: Demonstrate the efficacy and tolerability of escitalopram at a dose of 10 mg/day.

Additional reprints will be made available during FY04.

The following posters will be made available during FY04:

designed to include clinicians that may not be able to attend a dinner meeting due to scheduling conflicts or geographic challenges. Ten physicians from around the United States are convened by teleconference to discuss their experience with Lexapro and to hear specific clinical messages about Lexapro prescribing. Lexapro Peer Group moderators host each 90-minute TeleMAP session.

Both MAPs and TeleMAPs give Forest a way to reach healthcare professionals with strong, consistent product messages and to provide peer-to-peer dialogue. The Peer Group will dialogue with product management to facilitate ongoing training and provide new data to the moderators in order to create synergistic programs that leverage sales efforts as well. The participants of each program will receive a pre-meeting and post-meeting survey along with relevant literature provided by Lexapro Product Management at each event. Each participant will also receive an AMA approved honorarium valued at $100 for his or her participation.

Timing: Q1 – Q4
Quantity: MAPS – 480 TeleMAPS - 720
Cost Per Unit: MAPS - $4,800 TeleMaps - $3,300
Estimated Cost: $4,800,000

XXI. SPONSORSHIPS

A. ASSOCIATION SPONSORSHIPS

Funds have been allocated to aid the Professional Relations Group in their mission of establishing mutually beneficial long-term relationships with appropriate professionals and associations. These relationships will further best medical practices and policies in the treatment of depression and will optimize commercial opportunities for Lexapro. These relationships will also provide the basis for advocacy development and issues management, and will establish an appropriate environment for commercial and policy activities.

Additional information on associations of priority is provided as an appendix to this marketing plan (see *Appendix VII*).

Timing: Q1 – Q4
Estimated Cost: $1,900,000

B. EMORY UNIVERSITY UNRESTRICTED EUCATIONAL GRANT

The CNS marketing team has committed to Emory University to provide funds to the Department of Psychiatry and Behavioral Sciences (Department) at Emory for a period of three years; FY04 is the final year. The annual grant will create a fund for scientific discovery to support activity and programs related to junior faculty advancements within the Department and recognition of outstanding commitments in the field. Public relations activities surrounding this initiative to raise the awareness of Forest's support in the field of psychiatry will be explored.

Timing: Q4
Estimated Cost: $100,000

MEDICAL SCIENCE LIAISONS

The Medical Science Liaison (MSL) group for Forest Laboratories, Inc. is dedicated to providing thought leaders with the most current scientific and clinical information. Critical areas of contribution are developing and identifying strategic opportunities through phase IV research initiatives, publications, and establishing a close rapport with key members of the medical community important to Forests therapeutic areas of interest.

Comprised of, but not limited to, professional industry Medical Liaisons, PharmDs, and MDs, these positions form the outreach network emanating from the Medical and Marketing departments assuring continued interaction with local, national, and international opinion and thought leaders within the global medical community.

The 19 CNS MSLs are charged with establishing, developing, and maintaining long term sustainable working partnerships with members of the medical community whom may have regional, national, and/or international impact. Through these collaborative relationships, 19 MSLs promote awareness of medical knowledge and issues relating to the company's ongoing development efforts, and marketed products essential to the organization. This group also serves as a front line, advanced medical/technical force to be tapped into by regional/local opinion leaders. In addition, these individuals serve as a medical information resource to managed care efforts, and facilitate various company educational programs, most notably the speaker's bureau, regional advisory boards, and regional scientific programs and symposia.

A. MSL INVESTIGATOR GRANTS

MSL Investigator Grants cover the cost of Thought Leader Initiated Phase IV studies with Lexapro. In each of these cases, the investigator approaches an MSL with his/her concept and protocol for the study.

The detailed Lexapro Phase IV program is provided as an appendix to this marketing plan (see *Appendix V*).

Timing:	Q1 – Q4
Quantity:	45
Cost per study:	~$87,400
Estimated Cost:	$3,934,000

B. MSL REGIONAL CME SYMPOSIA

The MSLs will fund regionally developed and O/TL initiated CME symposia. Symposia will be funded based on the specific educational needs of the region. The symposia will be conducted in conjunction with academic health centers, medical associations and professional societies. Approximately 100-150 physicians, mostly psychiatrists, will be in attendance at each regional CME program. Cost for co-sponsorships is based on 2 co-sponsorships of established CME symposia per MSL in a year at a cost of $20,000 per co-sponsorship for a total cost of $40,000 per MSL per year. Since we have 19 MSLs, 2 co-sponsorships/MSL x $20,000/co-sponsership x 19 MSLs = approximately $750,000.

Timing:	Q1 – Q4
Quantity:	38 (2 per MSL; 19 MSLs)
Cost per grant:	$20,000
Estimated Cost:	$750,000

C. MSL UNRESTRICTED GRANTS

MSL unrestricted grants cover non-symposium educational programs, publication grants, travel grants to enable O/TLs to present Lexapro posters or presentations, support of local chapters of the APA at the request of an O/TL etc.

Timing: Q1 – Q4
Budget per MSL: ~$40,000 (about $2,100 per O/TL)
Estimated Cost: $750,000

D. REGIONAL GRANTS

Regional grant funds can be used to support local or regional symposia. RDs can provide up to $20,000 in the form of unrestricted educational grants.

Timing: Q1 – Q4
Cost: $20,000/RD (26)
Estimated Cost: $520,000

XXII. SEMINARS AND TRAINING

A. ANNOTATED MASTER VISUAL AID

The annotated sales aid provides helpful hints and ideas so that representatives can better understand the content of the Master Visual Aid. Each bullet point in the MVA is explained and helps to provide a consistent message to the field force. The annotated sales aid will be updated once for each POA. This piece is for training purposes only and will not be used in promotion.

Timing: Q1-Q4
Quantity: 11,000 (1,942 reps, 5/rep)
Cost Per Unit: $8.75
Estimated Cost: $90,000

B. ANNOTATED PACKAGE INSERT

The annotated package insert allows representatives the opportunity to review the key points of the package insert and the selling messages that the points reference. The annotated package inserts will be used train representatives on the revised package insert which will include GAD information when appropriate. This piece is for training purposes only and will not be used in promotion.

Timing: Q1-Q4
Quantity: 2,000
Cost Per Unit: $9.00
Estimated Cost: $15,000

C. ANNOTATED REPRINTS

As new reprints are selected for promotional use the representatives need to be trained on them. The annotated reprints allow representatives the opportunity to review the key points of the clinical study and the selling messages that the points reference. These pieces are for training purposes only and will not be used in promotion.

Timing: Q1-Q4
Quantity: 40,000
Cost Per Unit: $3.15
Estimated Cost: $120,000

D. MEETING WORKSHOPS

POA workshops will include PI and MVA reviews, clinical reprint and objection handling workshops, and role-plays. A vendor will be responsible for designing the workshops and will create all necessary leader's and participant's guides. Three POA meetings are scheduled for FY04.

Timing: Q1-Q4
Estimated Cost: $1,300,000

E. LEARNING SYSTEM- DEPRESSION

The Lexapro Depression Learning System has been developed in FY03 and each contains six written modules, five audiotapes, two videotapes, and a complete glossary. In FY04, we expect to reproduce approximately 1000 due to expansion and other training needs. The contents of each module are:

Module 1: *Fundamentals of Neuroanatomy and Neurotransmission*
Module 2: *Basics of Depression and Other Disorders*
Module 3: *Therapeutic Options for the Treatment of Depression*
Module 4: *The Competitors and the Marketplace*
Module 5: *Understanding Lexapro*
Module 6: *Celexa Overview*

Timing: Q1-Q3
Quantity: 1,000
Cost Per Unit: $100
Estimated Cost: $100,000

F. LEARNING SYSTEM - ANXIETY

The Lexapro Anxiety Learning System will contain 4 modules with audiotapes/videotapes. The GAD training will most likely begin in September 2003 and the Panic Disorder training in January 2004. The suggested contents of each module are:

Module 1: *Anxiety States*
Module 2: *Lexapro and GAD*
Module 3: *Competitors and the GAD Marketplace*
Module 4: *Competitors and the Panic Disorder Marketplace*

Timing: Q2-Q4
Quantity: 2,000
Cost Per Unit: $100
Estimated Cost: $200,000

XXIII. CONTESTS

A. CONTESTS

The Lexapro 20% market share club will be introduced to the field during the June 2003 National Sales Meeting. Each representative will receive an individually chosen high value gift item when they reach 20% new market share for Lexapro. Gift items are still under development but will likely be a small selection of carefully chosen items ranging from watches, wallets to candle stick holders. The ongoing Lexapro fast start contest will also be funded during FY04.

Timing: Q1-Q4
Estimated Cost: $350,000

XXIV. CONVENTIONS

The presence of a Lexapro booth display and promotional activities at medical conventions serves to increase awareness of Lexapro and its benefits for the treatment of depression with target audiences.

The detailed Lexapro convention schedule is provided as an appendix to this marketing plan (see *Appendix I*).

A. ABSTRACTS-ON-DISK

Forest will continue to sponsor the Abstracts-on-Disk program at the national meeting of the APA and ACNP. The Abstracts-on-Disk program makes all of the abstracts and new data submissions at the meeting available to meeting participants.

Timing: Q1-Q4
Quantity: 2
Estimated Cost: $45,000

B. ADVERTISEMENTS

A Lexapro advertisement will be placed in convention meeting booklets which are handed out to meeting participants. The advertisement is designed to be a reminder ad to physicians.

Timing: Q1-Q4
Estimated Cost: $190,000

C. BOOTH AND PANELS

The Lexapro convention booth panels will be updated in FY04 to reflect new Lexapro data. The purpose of the panels is to attract and retain booth traffic with captivating graphics and a powerful product message. Also included are panels for tabletop and in-line displays.

Timing: Q1-Q4
Estimated Cost: $100,000

D. DRAWS/GIVEAWAYS

Every professional association meeting has its own character. Appropriate booth activities for each major meeting will be developed in order to encourage booth traffic and complement the meeting's overall tone. Forest will take advantage of many meeting sponsored "door drops" by inserting a Lexapro promotional piece that is meeting-specific (symposia invitations, etc.), booth draw (giveaways, coupons, etc.) or brand message. The Lexapro Interactive Challenge will continue to be offered at various meetings. This activity is designed to engage meeting participants in a fun, learning activity where they learn about Lexapro's promotional messages.

Timing:	Q1 – Q4
Quantity:	26 conventions
Cost Per Unit:	$30,000
Estimated Cost:	$755,000

E. MEETING RECEPTIONS

Opportunities for Forest medical and marketing staff, as well as MSLs, to interact with opinion leaders (in both small and larger groups) will be scheduled at a number of major medical meetings during FY04. The purpose of these events is to develop personal relationships and provide intimate settings for scientific discussion. Programs may include dessert receptions with association members and other special events. Invitations will be issued via the MSLs. Among the meetings targeted in FY04 are the following:

* College of Psychiatric and Neurological Pharmacists (CPNP) – May 2003
* American Society of Health System Pharmacists (ASHP) – May 2003
* New Clinical Development Evaluation Unit (NCDEU) – May 2003
* American College of Neuropsychopharmacology (ACNP) – December 2003
* Anxiety Disorders Association of America (ADAA) – March 2004

Timing:	Q1 – Q4
Quantity:	5 receptions @ $24,000
Estimated Cost:	$120,000

XXV. PUBLICATIONS

Publications will be geared toward psychiatrists, PCPs, pharmacists, osteopaths, nurses, managed care organizations, LTC and others. Articles will appear in several formats, including original reports, review articles, and journal supplements. It is the brand team's intention to aggressively disseminate all new clinical data analyses when available.

A. ABSTRACTS AND POSTERS

Emerging preclinical and clinical data, as well as pooled analyses of Lexapro data, will be disseminated in poster (or occasionally oral/slide) format at all appropriate medical meetings. During FY04, approximately 70 abstracts/posters (both original and retread) will be presented at

U.S. meetings with a similar number of abstracts/posters presented at European meetings. The focus of the presentations in FY04 will be comparative and switch data in both depression and anxiety, clinical data in depression, GAD, panic disorder, SAD, and safety data. There will also be ample preclinical data and data from investigator initiated studies.

See *Appendix II* for the detailed publication plan

Timing:	Q1 – Q4
Quantity:	50
Cost Per Unit:	$6,000/poster
Estimated Cost:	$300,000

B. MANUSCRIPTS

As detailed in the Forest/Lundbeck Escitalopram Poster and Manuscript Preparation Plan (*Appendix II*), publications will be generated based on preclinical and clinical data, as it becomes available. Articles will appear in several formats, including original reports, review articles, and journal supplements. Approximately 10-12 manuscripts based on original data (generated by Forest) will be developed and submitted for publication during FY04, supporting the usefulness of Lexapro in the acute and long-term treatment of depression, and in the treatment of anxiety disorders (GAD, panic disorder, and SAD). There will also be publications on the comparative trials with venlafaxine, paroxetine, and sertraline, as well as the switch study with fluoxetine. Additionally, up to 10-12 review articles will be developed and submitted for publication during FY04. Articles will include reviews of Lexapro-specific pharmacology, efficacy in depression, efficacy in anxiety disorders, and safety including geriatric and pediatric patients (e.g., targeted to psychiatry, primary care, psychopharmacology, and pharmacy/formulary journals), as well as articles that include Lexapro data within the context of a broader review (e.g., safety in the geriatric population, current approaches to treating anxiety disorders, and selectivity of action).

See *Appendix II* for the detailed publication plan

Timing:	Q1 – Q4
Quantity:	24 manuscripts
Cost:	$700,000

C. PUBLICATION PLANNING AND STRATEGIC COUNSEL

Publication planning includes all agency time spent managing the publication grid, researching potential publication topics and attending all publication related activities and meetings. Strategic counsel and input to marketing activities as well as the development of strategic and tactical plans for the FY05 marketing plan.

Timing:	Q1 – Q4
Cost:	$350,000

D. ROUNDTABLES

Closed roundtables provide opportunities for a small group of experts to discuss topics especially relevant to the positioning and marketing of Lexapro. The deliverable from a roundtable is a journal supplement that is disseminated to a much larger audience. Closed roundtables can be held in conjunction with major medical meetings, or as stand-alone events. It is recommended that four

closed roundtables be held during FY04. Suggested topics include: 1) Panic Disorder; 2) SAD; 3) Geriatric; 4) Pediatric; and 5) Somatic symptoms associated with depression and anxiety.

Timing:	Q2 – Q4
Quantity:	4 events
Cost:	$500,000 (Includes event only)

E. SUPPLEMENTS

As part of a comprehensive publication plan, journal articles and supplements will be developed based on important content of particular Forest-sponsored symposia and roundtables. These published manuscripts will help disseminate relevant Lexapro data and messages to key target audiences, including psychiatrists, primary care physicians, managed care organizations, long-term care medical directors, and others. This amount assumes submission and publication of four supplements, and includes editorial support and page charges and does not include costs for reprints.

Timing:	Q2 – Q4
Quantity:	4
Cost Per Unit:	$162,500
Estimated Cost:	$650,000

APPENDIX I

CONVENTION SCHEDULE

APRIL		MIK = Medical Information Kiosk	
1 – 3	**AAN** – American Academy of Neurology Honolulu, HI	8,000	10x10
3 - 5	**PRI-MED WEST** Long Beach, CA	7,000	20x30
3 – 5	**ACP/ASIM** - American College of Physicians American Society of Internal Medicine San Diego, CA	6,000	20x30
9 – 12	**AMCP** – American Managed Care Pharmacy Minneapolis, MN	3,000	30x30 **MIK**
28 – 30	**ACOG** – American College of Obstetricians & Gynecologists New Orleans, LA	5,000	20x30
MAY			
14 - 16	**ASCP** - American Society of Consultant Pharmacists Midyear Geriatrics '03 –Tampa, FL	1,500	20x40
15 – 16	**AGS** - American Geriatrics Society Baltimore, MD	2,500	20x30
18 – 21	**APA** - American Psychiatric Association San Francisco, CA	16,000	60x80 **MIK**
JUNE			
9 – 10	**NADONA/LTC** Cincinnati, OH	400	10x20
19 – 21	**PRI-MED MIDWEST** Rosemont, IL	7,000	30x30
19 – 21	**US GERI** - US Geriatrics & Long-Term Care Congress San Francisco, CA	2,000	30x30

JULY		MIK = Medical Information Kiosk	
10 - 12	**Nurse Practitioner Symposium** Keystone, CO	1,500	10x30
AUGUST			
23 - 27	**NACDS** - National Association of Chain Drug Store Pharmacists Philadelphia, PA	2,600	10x30
SEPTEMBER			
OCTOBER			
2 – 4	**AAFP** - Am. Acad. of Family Physicians New Orleans, LA	6,500	30x50 MIK
2 – 4	**APNA** - American Psychiatric Nurse Assoc. Atlanta, GA	2,000	10x20
12 – 15	**AOA** - American Osteopathic Association New Orleans, LA	3,500	20x30
16 – 18	**PRI-MED MID-ATLANTIC** Washington, DC	5,000	20x30
19 – 22	**ANA** – American Neurological Association San Francisco, CA	1,300	10x20
10/30 – 11/1	**APA-I** - Am. Psychiatric Association – Institute of Psych. Services Boston, MA	2,200	20x30
??	**NAVY ACP** Location?	200	Table Top
NOVEMBER			
6 – 8	**US PSYCH & MHC** - US Psych & Mental Health Congress Orlando, FL	3,000	30x30
7 - 9	**PRI-MED EAST** Boston, MA	7,000	30x40
12 – 14	**ASCP Annual** - American Society of Consultant Pharmacists San Antonio, TX	2,000	30x30
??	**ARMY ACP** Location?	200	Table Top
DECEMBER			
8 – 11	**ASHP** - American Society of Health System Pharmacists New Orleans, LA	18,000	30x30

JANUARY		MIK = Medical Information Kiosk	
FEBRUARY			
13 – 15	**PRI-MED WEST** Long Beach, CA	8,000	30X40
MARCH			
1 – 4	**NMHCC** – National Managed Health Care Congress Washington, DC	3,000	10x30
4 – 6	**AMDA** – American Medical Directors Association Phoenix, AZ	1,200	20x20
12 – 15	**AAGP** - American Academy of Geriatric Psychiatry Atlanta, GA	1,250	30x30 **MIK**
??	**ADAA** - Anxiety Disorders of America Location??	350	10x20
28 – 30	**APhA** – American Pharmaceutical Association Seattle, WA	5,000	20x20

APPENDIX II

PUBLICATION PLAN

APPENDIX II

Publication Plan

Forest/Lundbeck Escitalopram Studies

Poster and Manuscript Preparation Plan

Study	Type*	Description	Study Director	Key Messages	Final Report	Abstract Due Date	Meeting/ Date	Manuscript Submission Date	Publication Date	Journal/Comments
PK Data										
PK-01	PK	Desipramine/Fluoxetine in vivo 2D6 pathway	FRX	Escitalopram has the lowest potential for drug interactions	Nov-00					Data insufficient to support publication To be included in PK review article
PK-02	PK	Ritonavir/no control in vivo 3A4 pathway	FRX	Escitalopram has the lowest potential for drug interactions	Jan-01		SOBP May-01			
							NCDEU May-01			
								Sep-02	Apr-03	Clinical Therapeutics, in press
PK-03	PK	Metoprolol/Paroxetine in vivo 2D6 pathway	FRX	Escitalopram has the lowest potential for drug interactions	Dec-00					Data insufficient to support publication To be included in PK review article
PK-04	PK	BE tablet marketing vs clinical	FRX	NA	Jan-01	NA	NA	NA	NA	NA
PK-05	PK	Pharmacokinetics in healthy elderly vs healthy young adult volunteers	FRX	Escitalopram has an excellent dosing profile	Sep-00					To be included in PK review article
PK-06	PK	BE oral solution vs tablet (food effect)	FRX	Escitalopram has an excellent dosing profile	Mar-01	NA	NA			To be included in PK review article
PK-07	PK	Drug interaction with warfarin	FRX	Escitalopram has the lowest potential for drug interactions	Apr-01					
PK-13	PK	Pharmacokinetics in pediatric patients	FRX	Escitalopram has an excellent dosing profile	Planned					
98106	PK	Single dose study to compare the pharmacokinetics and tolerability of escitalopram and citalopram	HLu	Escitalopram has an excellent dosing profile	Available		NCDEU May-01			To be included in PK review article
98107	PK	Double-blind, multi-dose, two-way crossover comparing the pharmacokinetics and tolerability of escitalopram and citalopram	HLu	Escitalopram has an excellent dosing profile	Available	NA	NA	NA	NA	Data insufficient to support publication To be included in PK review article
98113	PK	Bridging study of FRX and HLu clinical formulations and dosage form equivalence	HLu	NA	Sep-00	NA	NA	NA	NA	NA
99186	PK	Dose-proportionality at 10, 20 and 30 mg, also assesses effect of age	HLu	Escitalopram pharmacokinetics is linear and only modestly altered by age or gender	Oct-00					
In vitro P450 Isoenzymes	PK	R-CT, S-CT, R-DCT, and S-DCT are weak or negligible inhibitors of human cytochromes P450. This is unlikely to be of clinical importance		Escitalopram has the lowest potential for drug interactions	Available			Nov-00	Published Aug-01	vd Mollie et al . Drug Metab Dispos 2001,29 1102-9
							APA May-00			
							ASCPT Mar-01			
							SOBP May-01			
Clinical Data										

Study	Type*	Description	Study Director	Key Messages	Final Report	Abstract Due Date	Meeting/ Date	Manuscript Submission Date	Publication Date	Journal/Comments
MD-01	D	Fixed Dose Comparison of the Safety and Efficacy of Escitalopram, Citalopram, and Placebo in the Treatment of Major Depressive Disorder	FRX	Escitalopram represents a new more selective and/or potent generation of SSRIs	Dec-00			Submitted Mar-01	Published Apr-02	Burke et al., J Clin Psychiatry 2002, 63:331-336
				Escitalopram is an effective first line treatment for depression			ACNP Dec-00			primary results poster
				Escitalopram has a favorable side effect profile Escitalopram has an excellent dosing profile Escitalopram is the active isomer of citalopram in terms of antidepressant effect			APA May-01			results poster with additional posters that pool data from: MD-01, MD-02 and 99003 (efficacy comparison of S-CT with CT) MD-01, MD-02 and 99003 (comparison of effects of S-CT and CT on anxiety Sx)
				Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer			NCDEU May-01			primary results poster
				Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability			WCBP Jul-01			results poster with additional posters that pool data from: MD-01, MD-02 and 99003 (efficacy comparison of S-CT with CT) MD-01, MD-02 (comparison of effects of S-CT and CT on anxiety Sx) MD-01, MD-02, 99001, 99003 (safety comparison of S-CT and CT)
							APA-I Oct-01			Poster pools data from MD-01, MD-02 (comparison of effects of S-CT and CT on anxiety Sx)
							SCNP Apr-02			Poster based on MADRS single item analysis
							AEP May-02			Poster pools data from MD-01, MD-02, 99003 (efficacy comparison w/ CT)
MD-01 cont							APA May-02			Poster pools data from MD-01, MD-02, 99001, 99003 (safety database)
							NCDEU Jun-02			Poster pools data from MD-01, MD-02, 99001, 99003 (safety database) w/ SCT vs CT comparison
							CINP Jun-02			Poster pools data from MD-01, MD-02, 99003 (efficacy in severely ill patients)
							WCP Aug-02			Poster pools data from MD-01, 99001 for MADRS single item analysis Poster pools data from MD-01, MD-02, 99001, 99003 (efficacy in severely ill patients)

Study	Type*	Description	Study Director	Key Messages	Final Report	Abstract Due Date	Meeting/ Date	Manuscript Submission Date	Publication Date	Journal/Comments
							ECNP Oct-02			Poster pools data from MD-01, MD-02, 99001, 99003 (efficacy in severely ill patients) Poster pools data from MD-01, 99001 (onset of effect in fixed dose studies)
							ICGP Oct-02			Poster pools data from MD-01, MD-02, 99001, 99003, 99024 (safety in geriatric patients)
							AAGP Mar-03			Poster pools data from MD-01, MD-02, 99001, 99003, 99024 (safety in geriatric patients)
						Feb-03	CPNP Apr-03			Poster pools data from MD-01, MD-02, 99001, 99003 (efficacy in severely ill patients)
MD-02	D	Flexible Dose Comparison of the Safety and Efficacy of Escitalopram, Citalopram, and Placebo in the Treatment of Major Depressive Disorder	FRX	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is an effective first line treatment for depression Escitalopram has a favorable side effect profile Escitalopram has an excellent dosing profile Escitalopram is the active isomer of citalopram in terms of antidepressant effect Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moety, the R-enantiomer	Dec-00		APA May-01			posters pool data from MD-01, MD-02 and 99003 (efficacy comparison of S-CT with CT) MD-01, MD-02 and 99003 (comparison of effects of S-CT and CT on anxiety Sx)
							WCBP Jul-01			posters pool data from MD-01, MD-02 and 99003 (efficacy comparison of S-CT with CT) MD-01, MD-02 (comparison of effects of S-CT and CT on anxiety Sx) MD-01, MD-02, 99001, 99003 (safety comparison of S-CT and CT)
							APA-I Oct-01			Poster pools data from MD-01, MD-02 (comparison of effects of S-CT and CT on anxiety Sx)
							ACNP Dec-01			Poster pools data from MD-02, 99003 (efficacy comparison w/ CT in flexible dose studies)
MD-02 cont							AEP May-02			Poster pools data from MD-01, MD-02, 99003 (efficacy comparison w/ CT)
							APA May-02			Poster pools data from MD-01, MD-02, 99001, 99003 (safety database)
							NCDEU Jun-02			Poster pools data from MD-01, MD-02, 99001, 99003 (safety database) w/ SCT vs CT comparison
							CNP Jun-02			Poster pools data from MD-01, MD-02, 99003 (efficacy in severely ill patients)
							WCP Aug-02			Poster pools data from MD-01, MD-02, 99001, 99003 (efficacy in severely ill patients)

Study	Type*	Description	Study Director	Key Messages	Final Report	Abstract Due Date	Meeting/ Date	Manuscript Submission Date	Publication Date	Journal/Comments
							ECNP Oct-02			Poster pools data from MD-01, MD-02, 99001, 99003 (efficacy in severely ill patients)
							ICGP Oct-02			Poster pools data from MD-01, MD-02, 99001, 99003, 99024 (safety in geriatric patients)
							AAGP Mar-03			Poster pools data from MD-01, MD-02, 99001, 99003, 99024 (safety in geriatric patients)
						Feb-03	CPNP Apr-03			Poster pools data from MD-01, MD-02, 99001, 99003 (efficacy in severely ill patients)
MD-03	D	Placebo-Controlled Evaluation of the Safety and Efficacy of Escitalopram in the Prevention of Depression Relapse	FRX	Escitalopram represents a new more selective and/or potent generation of SSRIs	Oct-01			Draft Jan-03		J Clin Psychiatry
				Escitalopram is an effective first line treatment for depression						Possible 2nd publication on withdrawal/ discontinuation effects
				Escitalopram has a favorable side effect profile			ACNP Dec-01			
				Escitalopram has an excellent dosing profile			AEP May-02			
				Escitalopram is the active isomer of citalopram in terms of antidepressant effect			NCDEU Jun-02			
				Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability			CINP Jun-02			Primary results poster and 2nd poster with switch data
							WCP (WPA) Aug-02			Primary results poster and 2nd poster with switch data
							APA-1 Oct-02			
							ECNP Oct-02			Poster pools data from MD-03, 99002, 99022, (long-term tolerability)
						Feb-03	CPNP Apr-03			
MD-04	A	Flexible Dose Comparison of the Safety and Efficacy of Escitalopram, Citalopram, and Placebo in the Treatment of Panic Disorder	FRX	Escitalopram represents a new more selective and/or potent generation of SSRIs	Feb-02			Draft Jan-03		J Clin Psychiatry, submitted
				Escitalopram is an effective first line treatment for anxiety disorders			ADAA Mar-02			
				Escitalopram has a favorable side effect profile			APA May-02			
				Escitalopram has an excellent dosing profile			NCDEU Jun-02			
				Escitalopram is the active isomer of citalopram in terms of anxiolytic effect			CINP Jun-02			
				Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer			WCP (WPA) Aug-02			Primary results poster 2nd poster pools data from MD-04, MD-05, 99012, preclinical (anxiolytic effects predicted by animal models)

Revised March 5, 2003

Study	Type*	Description	Study Director	Key Messages	Final Report	Abstract Due Date	Meeting/ Date	Manuscript Submission Date	Publication Date	Journal/Comments
							APA-I Oct-02			Primary results poster 2nd poster pools data from MD-04, MD-05, 99012, preclincal (anxiolytic effects predicted by animal models)
							ECNP Oct-02			Poster pools data from MD-04, MD-05, 99012, preclincal (anxiolytic effects predicted by animal models)
						Nov-02	ADAA Mar-03			Poster pools data from MD-04, MD-05, 99012, preclincal (anxiolytic effects predicted by animal models)
MD-05	A	Flexible Dose Comparison of Safety & Efficacy of S-CT vs Placebo in the Treatment of Generalized Anxiety Disorder	FRX	Escitalopram represents a new more selective and/or potent generation of SSRIs	Dec-01			Draft Jan-03		Publish as part of pooled analyses of GAD trials?
				Escitalopram is an effective first line treatment for anxiety disorders			ADAA Mar-02			
				Escitalopram has a favorable side effect profile			NCDEU Jan-02			
				Escitalopram has an excellent dosing profile			CINP Jun-02			
				Escitalopram is the active isomer of citalopram in terms of anxiolytic effect			WCP (WPA) Aug-02			Primary results poster 2nd poster pools data from MD-04, MD-05, 99012, preclincal (anxiolytic effects predicted by animal models)
							APA-I Oct-02			Poster pools data from MD-04, MD-05, 99012, preclincal (anxiolytic effects predicted by animal models)
							ECNP Oct-02			Poster pools data from MD-04, MD-05, 99012, preclincal (anxiolytic effects predicted by animal models)
							ACNP Dec-02			Poster pools data from MD-05, MD-06, MD-07
						Nov-02	ADAA Mar-03			Poster pools data from MD-04, MD-05, 99012, preclincal (anxiolytic effects predicted by animal models) Additional poster pools data from MD-05, MD-06, MD-07
						Feb-03	CPNP Apr-03			Poster pools data from MD-05, MD-06, MD-07
						Jan-03	APA May-03			Poster pools data from MD-05, MD-06, MD-07
MD-06	A	Flexible Dose Comparison of Safety & Efficacy of S-CT vs Placebo in the Treatment of Generalized Anxiety Disorder	FRX	Escitalopram represents a new more selective and/or potent generation of SSRIs	Oct-02			Draft Jan-03		Publish as part of pooled analyses of GAD trials?
				Escitalopram is an effective first line treatment for anxiety disorders			ACNP Dec-02			Poster pools data from MD-05, MD-06, MD-07
				Escitalopram has a favorable side effect profile		Nov-02	ADAA Mar-03			Poster pools data from MD-05, MD-06, MD-07

Study	Type*	Description	Study Director	Key Messages	Final Report	Abstract Due Date	Meeting/ Date	Manuscript Submission Date	Publication Date	Journal/Comments
				Escitalopram has an excellent dosing profile		Feb-03	CPNP Apr-03			Poster pools data from MD-05, MD-06, MD-07
				Escitalopram is the active isomer of citalopram in terms of anxiolytic effect		Jan-03	APA May-03			Poster pools data from MD-05, MD-06, MD-07
MD-07	A	Flexible Dose Comparison of Safety & Efficacy of S-CT vs Placebo in the Treatment of Generalized Anxiety Disorder	FRX	Escitalopram represents a new more selective and/or potent generation of SSRIs	Oct-02			Draft Jan-03		Depression and Anxiety, submitted Also publish as part of pooled analysis of GAD trials?
				Escitalopram is an effective first line treatment for anxiety disorders			ACNP Dec-02			Primary efficacy poster Additional poster pools data from MD-05, MD-06, MD-07
				Escitalopram has a favorable side effect profile		Nov-02	ADAA Mar-03			Primary efficacy poster Additional poster pools data from MD-05, MD-06, MD-07
				Escitalopram has an excellent dosing profile		Feb-03	CPNP Apr-03			Primary efficacy poster Additional poster pools data from MD-05, MD-06, MD-07
				Escitalopram is the active isomer of citalopram in terms of anxiolytic effect		Jan-03	APA May-03			Primary efficacy poster Additional poster pools data from MD-05, MD-06, MD-07
MD-08	D	20 mg Continuation in S-CT Nonresponders from Recurrence Study	FRX	Escitalopram represents a new more selective and/or potent generation of SSRIs	Nov-02					
MD-09	D	Flexible Dose, Fixed dose comparison of escitalopram and fluoxetine in patients with MDD, double blind, randomized, parallel group	FRX	Escitalopram represents a new more selective and/or potent generation of SSRIs	Oct-02					
				Escitalopram is an effective first line treatment for depression						
				Escitalopram has a favorable side effect profile						
				Escitalopram is the active isomer of citalopram in terms of antidepressant effect						
MD-10	D	Psychomotor / Alcohol Interaction, Monitor plasma levels of escitalopram and alcohol in healthy volunteers	FRX	Escitalopram does not potentiate effects of alcohol	Oct-02	Oct-02	SoBP May-03			
				Escitalopram has a favorable side effect profile		Jan-03	NCDEU May-03			
MD-11	D	Depression Recurrence/Switch	FRX	Escitalopram represents a new more selective and/or potent generation of SSRIs	Feb-02					
		Open-label recurrence in responders after switch from other SSRIs to S-CT		Escitalopram is an effective first line treatment for depression	Apr-02		CINP Jun-02			Response to S-CT in previous AE drops with other SSRIs
		Response to S-CT in previous non-responders to other SSRIs		Escitalopram has a favorable side effect profile	Apr-02		WCP (WPA) Aug-02			Response to S-CT in previous AE drops with other SSRIs
		Response to S-CT in previous AE drops with other SSRIs		Escitalopram is the active isomer of citalopram in terms of antidepressant effect	Aug-02		ECNP Oct-02			Response to S-CT in previous AE drops with other SSRIs
		Double-blind recurrence in S-CT responders					APA-I Oct-02			Response to S-CT in previous AE drops with other SSRIs

Revised March 5, 2003

Study	Type*	Description	Study Director	Key Messages	Final Report	Abstract Due Date	Meeting/ Date	Manuscript Submission Date	Publication Date	Journal/Comments
MD-12	D	Venlafaxine comparative	FRX		Aug-03					
MD-15	D	Pediatric	FRX		Jan-04					
MD-16	D	9-week double blind comparison of escitalopram and fluoxetine in MDD	FRX	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is an effective first line treatment for depression Escitalopram has a favorable side effect profile Escitalopram has an excellent dosing profile Escitalopram is the active isomer of citalopram in terms of antidepressant effect Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability	Jan-02					
MD-17	A	Open Label Extension of Safety & Efficacy of S-CT in the Treatment of Generalized Anxiety Disorder	FRX	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is an effective first line treatment for anxiety disorders Escitalopram has a favorable side effect profile Escitalopram has an excellent dosing profile	Nov-02					
				Escitalopram is the active isomer of citalopram in terms of anxiolytic effect						
MD-18	D	Sertraline comparative	FRX		Aug-03					
MD-19	D	Open Label Extension of Safety & Efficacy of S-CT in Depression	FRX	Escitalopram represents a new more selective and/or potent generation of SSRIs	Oct-03					
MD-20	A	Comparison of Safety & Efficacy of S-CT vs Paroxetine in the Treatment of Generalized Anxiety Disorder	FRX	Escitalopram represents a new more selective and/or potent generation of SSRIs	Apr-03					
MD-21	D	Fluoxetine Switch	FRX	Escitalopram represents a new more selective and/or potent generation of SSRIs	Jun-03					
MD-26	D	In-patient depression	FRX	Escitalopram represents a new more selective and/or potent generation of SSRIs	Feb-04	Jan-03	APA May-03			
						Jan-03	NCDEU May-03			
99001	D	10 mg fixed dose for MDD	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is an effective first line treatment for depression	Available			Dec-01	May-02	Wade et al., International Clinical Psychopharmacology 2002;17 95-102
							SCNP Apr-01			S-CT 10 mg vs placebo

Study	Type*	Description	Study Director	Key Messages	Final Report	Abstract Due Date	Meeting/ Date	Manuscript Submission Date	Publication Date	Journal/Comments
				– 10 mg dose – primary care setting – no difference in AE drop outs vs placebo			WCBP Jul-01			S-CT 10 mg vs placebo additional poster pools data from MD-01, MD-02, 99001, 99003 (safety comparison of S-CT and CT)
				Escitalopram has a favorable side effect profile			Forum on Mood & Anxiety Disorders Nov-01			SCT 10 mg vs placebo
				Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability						
99001 cont							APA May-02			Poster pools data from MD-01, MD-02, 99001, 99003 (safety database)
							NCDEU Jun-02			S-CT 10 mg vs placebo 2nd poster pools data from MD-01, MD-02, 99001, 99003 (safety database) w/ SCT vs CT comparison
							CINP Jun-02			Poster pools data from MD-01, MD-02, 99001, 99003 (efficacy in severely ill patients)
							WCP (WPA) Aug-02			Poster pools data from MD-01, 99001 for MADRS single item analysis
							ECNP Oct-02			Poster pools data from MD-01, 99001 for onset of effect in fixed dose studies
							ICGP Oct-02			Poster pools data from MD-01, MD-02, 99001, 99002, 99024 (safety in geriatric patients)
							AAGP Mar-03			Poster pools data from MD-01, MD-02, 99001, 99003, 99024 (safety in geriatric patients)
99002	B	Open long-term treatment from 99001 or 99003	HLs	Escitalopram represents a new more selective and/or potent generation of SSRIs	Feb-02			Jul-02	Mar-03	TBD
				Escitalopram is an effective first line treatment for depression			SCNP Apr-02			
				Escitalopram has a favorable side effect profile			CINP Jun-02			
				Escitalopram has an excellent dosing profile			WCP (WPA) Aug-02			
				Escitalopram is the active isomer of citalopram in terms of antidepressant/anxiolytic effect			ECNP Oct-02			Primary results, long-term efficacy Poster pools data from MD-03, 99002, 99022, (long-term tolerability)
				Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability			IPMAD Nov-02			Poster present long-term efficacy of escitalopram Second poster presents data on switch from citalopram

Study	Type*	Description	Study Director	Key Messages	Final Report	Abstract Due Date	Meeting/ Date	Manuscript Submission Date	Publication Date	Journal/Comments
						Jan-03	SCNP Apr-03			Long-term efficacy of escitalopram
99003	D	Flexible-dose comparative of citalopram and escitalopram	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs	Available			TBD	TBD	TBD
				Escitalopram is an effective first line treatment for depression					Published May-01	4-week data combined with PCL-104 Montgomery et al Pharmacol Toxicol 2001;88 292-296
				Escitalopram has an excellent dosing profile			SCNP Apr-01			posters 4-week "fixed" dose, 8-week flexible dose
				Escitalopram is the active isomer of citalopram in terms of antidepressant effect Escitalopram has a favorable side effect profile			APA May-01			poster 4-week "fixed" dose additional poster pools data from MD-01, MD-02 and 99003 (efficacy comparison of S-CT with CT) MD-01, MD-02 and 99003 (comparison of effects of S-CT and CT on anxiety Sx)
				Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the *R*-enantiomer			WCBP Jul-01			posters 4-week "fixed" dose additional posters pool data from MD-01, MD-02 and 99003 (efficacy comparison of S-CT with CT) and MD-01, MD-02, 99001, 99003 (safety comparison of S-CT and CT)
				Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability			APA-I Oct-01			Poster pools data from MD-01, MD-02, 99003 (comparison of effects of S-CT and CT on anxiety Sx)
							ACNP Dec-01			Poster pools data from MD-02, 99003 (efficacy comparison w/ CT in flexible dose studies)
99003 cont							AEP May-02			Poster pools data from MD-01, MD-02, 99003 (efficacy comparison w/ CT)
							APA May-02			Poster pools data from MD-01, MD-02, 99001, 99003 (safety database)
							NCDEU Jun-02			Poster pools data from MD-01, MD-02, 99001, 99003 (safety database) w/ SCT vs CT comparison
							CINP Jun-02			Poster pools data from MD-01, MD-02, 99001, 99003 (efficacy in severely ill patients)
							WCP (WPA) Aug-02			Poster pools data from MD-01, MD-02, 99003 (efficacy in severely ill patients)
							ECNP Oct-02			Primary results poster 2nd poster pools data from MD-01, MD-02, 99003 (efficacy in severely ill patients)
							ICGP Oct-02			Poster pools data from MD-01, MD-02, 99001, 99003, 99024 (safety in geriatric patients)
							IFMAD Nov-02			Primary results poster

Study	Type*	Description	Study Director	Key Messages	Final Report	Abstract Due Date	Meeting/ Date	Manuscript Submission Date	Publication Date	Journal/Comments
							AAGP Mar-03			Poster pools data from MD-01, MD-02, 99001, 99003, 99024 (safety in geriatric patients)
						Jan-03	SCNP Apr-03			Primary results poster
						Feb-03	CPNP Apr-03			Poster pools data from MD-01, MD-02, 99001, 99003 (efficacy in severely ill patients)
99022	D	6-month comparative treatment of citalopram and escitalopram	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs	Sep-01					
				Escitalopram is an effective first line treatment for depression			CINP Jun-02			Poster pools data from MD-03, 99002, 99022, (long-term tolerability)
				Escitalopram has a favorable side effect profile			WCP (WPA) Aug-02			Poster pools data from MD-03, 99002, 99022, (long-term tolerability)
		-- will include PE assessment		Escitalopram has an excellent dosing profile			ECNP Oct-02			Poster pools data from MD-03, 99002, 99022, (long-term tolerability)
				Escitalopram is the active isomer of citalopram in terms of antidepressant effect			IFMAD Nov-02			
				Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer		Jan-03	SCNP Apr-03			
				Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability		Mar-03	ECNP Sep-03			
99024	D	Fixed dose comparison of sCT or fluoxetine vs placebo in elderly patients with MDD	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs	Sep-01					Data insufficient for publication
				Escitalopram is an effective first line treatment for depression			ICGP Oct-02			Poster pools data from MD-01, MD-02, 99001, 99003, 99024 (safety in geriatric patients)
				Escitalopram has a favorable side effect profile			AAGP Mar-03			Poster pools data from MD-01, MD-02, 99001, 99003, 99024 (safety in geriatric patients)
				Escitalopram has an excellent dosing profile						
				Escitalopram is the active isomer of citalopram in terms of antidepressant effect						
99012	A	Placebo-Controlled Evaluation of the Safety and Efficacy of Escitalopram in Social Anxiety Disorder, Flex dose 10-20 mg escitalopram vs placebo	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs	Nov-01			Dec-01	TBD	TBD
				Escitalopram is an effective first line treatment for anxiety disorders			ADAA Mar-02			
				Escitalopram has a favorable side effect profile			SCNP Apr-02			
				Escitalopram has an excellent dosing profile			AEP May-02			
				Escitalopram is the active isomer of citalopram in terms of anxiolytic effect			APA May-02			

Study	Type*	Description	Study Director	Key Messages	Final Report	Abstract Due Date	Meeting/ Date	Manuscript Submission Date	Publication Date	Journal/Comments
							CINP Jun-02			
							WCP Aug-02			Primary results poster 2nd poster pools data from MD-04, MD-05, 99012, preclinical (anxiolytic effects predicted by animal models)
							ECNP Oct-02			Poster pools data from MD-04, MD-05, 99012, preclinical (anxiolytic effects predicted by animal models)
							APA-I Oct-02			Primary results poster 2nd poster pools data from MD-04, MD-05, 99012, preclinical (anxiolytic effects predicted by animal models)
						Nov-02	ADAA Mar-03			Poster pools data from MD-04, MD-05, 99012, preclinical (anxiolytic effects predicted by animal models)
99087		Ventalaxine	HLu		Jun-02		ECNP Oct-02			
							IFMAD Nov-02			
						Jan-03	SCNP Apr-03			
						Jan-03	ISPOR May-03			PrE evaluation
99187		Piggyback	HLu		Nov-01					
99256		Elderly long-term	HLu		Sep-02					
99269	A	Placebo-Controlled Evaluation of the Safety and Efficacy of Escitalopram in Social Anxiety Disorder, Flex dose 10-20 mg escitalopram vs placebo, relapse prevention	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs	Feb-03	Nov-02	ADAA Mar-03			Primary results poster and two PrE posters
				Escitalopram is an effective first line treatment for anxiety disorders		Jan-03	APA May-03			Primary results poster and PrE poster
				Escitalopram has a favorable side effect profile		Jan-03	NCDEU May-03			Primary results poster
				Escitalopram has an excellent dosing profile		Jan-03	ISPOR May-03			PrE evaluation of response vs non-response
				Escitalopram is the active isomer of citalopram in terms of anxiolytic effect		Mar-03	ECNP Sep-03			Primary results poster and two PrE posters
99270	A	Placebo-Controlled Evaluation of the Safety and Efficacy of Escitalopram in Social Anxiety Disorder, Dose-finding 5 mg, 10 mg, 15 mg escitalopram, placebo and paroxetine	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs	Mar-03	Jan-03	Apr-03			
				Escitalopram is an effective first line treatment for anxiety disorders		Mar-03	ECNP Sep-03			
				Escitalopram has a favorable side effect profile						
				Escitalopram has an excellent dosing profile						
				Escitalopram is the active isomer of citalopram in terms of anxiolytic effect						

Revised March 5, 2003

Study	Treat	Description	Study Director	Key Messages	Final Report	Abstract Due Date	Meeting/ Date	Manuscript Submission Date	Publication Date	Journal/Comments
99505	D	Paroxetine	HLu		Mar-03					
99788	A	GAD relapse prevention	HLu		Q1-2005					
99815	A	GAD dose finding	HLu		Q2-2004					
99849	D	PhMD	HLu		Mar-04					
99906	A	Pharmacokinetics for 99788	HLu		Q1-2005					
Pharmacology Data										
PCL-001	A	Panic-like Anxiety, footshock induced ultrasonic vocalization. CT and S-CT (potently inhibited footshock induced ultrasonic vocalization The maximum inhibition was 60-70% for CT and S-CT inhibited completely. RCT inhibited vocalization with an approximately 15 times lower potency than S-CT Comparators: SSRIs, RCT & 5-HTP augmentation	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is an effective first line treatment for anxiety disorders Escitalopram is the active isomer of citalopram in terms of anxiolytic effect	Available			Jul-01		Journal TBD manuscript combines data from PCL-001, PCL-002, PCL-003, PCL-101, PCL-103, PCL-107, PCL-302, and in vitro uptake inhibition
							ACNP Dec-00			poster combines data from PCL-001, PCL-002, PCL-303
							APA May-01			
							NCDEU Jun-01			
							WCBP Jul-01			
							SCNP Apr-02			Poster combines data from PCL-001, PCL-003
							CINP Jun-02			Poster combines data from PCL-001, 003, 101, 103, SSRIs in anxiety, depression, aggression
							ECNP Oct-02			Poster combines data from PCL-001, 003, 101, 103, SSRIs in anxiety, depression, aggression
PCL-002	A	GAD (Black and white box) rat and mice, Comparators: SSRIs, RCT, 5-HTP augmentation	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is an effective first line treatment for anxiety disorders Escitalopram is the active isomer of citalopram in terms of anxiolytic effect	Available			Jul-01		Journal TBD manuscript combines data from PCL-001, PCL-002, PCL-003, PCL-101, PCL-103, PCL-107, PCL-302, and in vitro uptake inhibition
							ACNP Dec-00			poster combines data from PCL-001, PCL-002, PCL-303
							APA May-01			
							NCDEU Jun-01			
							WCBP Jul-01			
							ECNP Oct-02			Poster combines data from PCL-001, 003, 101, 103, SSRIs in anxiety, depression, aggression
PCL-003	A	Panic-like Anxiety, footshock induced ultrasonic vocalization. Comparators: R-fluoxetine, venlafaxine, reboxetine	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is an effective first line treatment for anxiety disorders	Available			Jul-01		Journal TBD manuscript combines data from PCL-001, PCL-002, PCL-003, PCL-101, PCL-103, PCL-107, PCL-302, and in vitro uptake inhibition
							SCNP Apr-02			Poster combines data from PCL-001, PCL-003
							CINP Jun-02			Poster combines data from PCL-001, 003, 101, 103, SSRIs in anxiety, depression, aggression

Revised March 5, 2003

Study	Type*	Description	Study Director	Key Messages	Final Report	Abstract Due Date	Meeting/ Date	Manuscript Submission Date	Publication Date	Journal/Comments
							ECNP Oct-02			Poster combines data from PCL-001, 003, 101, 102, SSRIs in anxiety, depression, aggression
PCL-004	A	Panic-like Anxiety, footshock induced ultrasonic vocalization Comparators RCT & S-CT	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is an effective first line treatment for anxiety disorders Escitalopram is the active isomer of citalopram in terms of anxiolytic effect	Available					poster combines data from PCL-003, PCL-004, PCL-005, PCL-006
PCL-005	A	Panic-like Anxiety, Dorsal Periaqueductal Grey Stimulation (DPAG), where panic like attacks are induced by electric stimulation in the periaqueductal grey area in the brain Acute effect of SSRIs The model is under development and should be available for assessments in Q3 02 Plans include dose response S-, R-, R,S-CT, combinations S- and R- ratios 1:2 and 1:4	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is an effective first line treatment for anxiety disorders Escitalopram is the active isomer of citalopram in terms of anxiolytic effect	Available		SoBP May-02			poster combines data from PCL-003, PCL-004, PCL-005, PCL-006
							CINP Jun-02			
							WCP (WPA) Aug-02			
PCL-006	A	OCD, Polydipsia, rat Abnormal drinking behavior is induced by restricted and scheduled availability of food Applicable as model onset of action Comparators R-fluoxetine, RCT, paroxetine, sertraline, venlafaxine	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is an effective first line treatment for anxiety disorders Escitalopram is the active isomer of citalopram in terms of anxiolytic effect Escitalopram has a faster onset of action	Available					
PCL-007	A	GAD, GABAA g2-receptor deficient mice, conditioned fear stress model New investigator needed	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is an effective first line treatment for anxiety disorders Escitalopram is the active isomer of citalopram in terms of anxiolytic effect	Planned					
PCL-008	A	GAD, Conditioned fear stress, rat, Fanselow, UCLA	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is an effective first line treatment for anxiety disorders Escitalopram is the active isomer of citalopram in terms of anxiolytic effect			ECNP Oct-02			May be stand-alone
PCL-009	A	5-HT1A receptor knockout New investigator needed	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is an effective first line treatment for anxiety disorders Escitalopram is the active isomer of citalopram in terms of anxiolytic effect	Planned					
PCL-010	A	PMDD, Progesterone metabolism in vitro, Comparators RCT, fluoxetine	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs	Available					Possibly for ACOG May-02

Revised March 5, 2003

Study	Type*	Description	Study Director	Key Messages	Final Report	Abstract Due Date	Meeting/ Date	Manuscript Submission Date	Publication Date	Journal/Comments
							CINP Jul-00			
							CINP Jun-02			Poster combines data from PCL-001, 003, 101, 103, SSRIs in anxiety, depression, aggression
							ECNP Oct-02			Poster combines data from PCL-001, 003, 101, 103, SSRIs in anxiety, depression, aggression
PCL-102	D	Depression/Onset of action, Agnostic Behavior Rat, Paul Mitchell Results from the first study indicate that escitalopram is more than twice as potent as CT in acute test. The chronic study suggests an antidepressant profile It is recommended to perform follow up studies (follow up study is PCL-106) 1) Complete dose response relationship S- and R, S-CT, test RCT alone, test combination of R and S, ratio 4:1 2) Onset of action study escitalopram vs CT with daily assessment for 7 days	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is an effective first line treatment for depression Escitalopram is the active isomer of citalopram in terms of antidepressant effect Escitalopram has a faster onset of antidepressant action Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability	Available		ACNP Dec-00 SOBP May-01 WCBP Jul-01			poster combines data from PCL-102, PCL-103 and PCL-303 poster combines data from PCL-102, PCL-106
								Sep-01		manuscript can combine data from PCL-102 with PCL-106
PCL-103	D	Depression, isolated aggressive mice Neither CT nor its enantiomers inhibited aggressive behavior of isolated mice CT and S-CT but not RCT inhibited aggressive behavior potently if they were co-administered with l-5-HTP Comparators: SSRIs, RCT, l-5-HTP augmentation	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is an effective first line treatment for depression Escitalopram is the active isomer of citalopram in terms of antidepressant effect Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability	Available		ACNP Dec-00 SOBP May-01 CINP Jun-02			poster combines data from PCL-102, PCL-103 and PCL-303 Poster combines data from PCL-001, 003, 101, 103, SSRIs in anxiety, depression, aggression
PCL-104	D	Depression/Onset of action, Effect in chronic mild stress model, rat, M. Papp, Comparators: CT, R-fluoxetine S-CT twice as potent as R-fluoxetine, onset at week 1 2 options S-CT compared with R-fluoxetine S-CT compared with CT	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is an effective first line treatment for depression Escitalopram is the active isomer of citalopram in terms of antidepressant effect Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability Escitalopram has a faster onset of antidepressant action	Available		APA May-01 NCDEU May-01 WCBP Jul-01 Forum on Mood & Anxiety Disorders Nov-01 SOBP May-02			
PCL-105	D	Depression/Onset of action, HPA axis function. Assessment of baseline and stress induced changes of mRNA POMC expression in anterior pituitary and serum corticosterone in rats treated acutely and chronically, respectively, with S or R-enantiomer	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is an effective first line treatment for depression Escitalopram is the active isomer of citalopram in terms of antidepressant effect	Ongoing, may be de-continued					Psychoneuroendocrinology

Study	Type*	Description	Study Director	Key Messages	Final Report	Abstract Due Date	Meeting/ Date	Manuscript Submission Date	Publication Date	Journal/Comments
				Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability						
				Escitalopram has a faster onset of antidepressant action						
PCL-106	D	Depression/Onset of action, Agnostic Behavior Paul Mitchell. Results from the trial study indicate that escitalopram is more than twice as potent as citalopram in acute test	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs	Available			Sep-01		manuscript can combine data from PCL-106 with PCL- 102
		The chronic study suggests an antidepressant profile. It is recommended to preform follow up studies.		Escitalopram is an effective first line treatment for depression			APA May-01			poster combines data from PCL-106 and PCL-107
		1) Complete dose response relationship S- and R, S-citalopram, test R-citalopram alone test combination of R and S, ratio 4:1		Escitalopram is the active isomer of citalopram in terms of antidepressant effect			WCBP Jul-01			poster combines data from PCL-102 with PCL- 106
		2) Onset of action study escitalopram vs citalopram with daily assessment for 7 days Comperator CT, RCT		Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability Escitalopram has a faster onset of antidepressant action						
PCL-107	D	Depression, Forced swim test, mice R-fluoxetine, venlafaxine	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs	Available			Jul-01		Journal TBD manuscript combines data from PCL-001, PCL-002, PCL-003, PCL-101, PCL-103, PCL-107, PCL-302, and In vitro uptake inhibition
				Escitalopram is an effective first line treatment for depression Escitalopram is the active isomer of citalopram in terms of antidepressant effect						
PCL-108	D	Depression, Chronic mild stress. Venlafaxine, sertraline, paroxetine	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is an effective first line treatment for depression Escitalopram is the active isomer of citalopram in terms of antidepressant effect	Planned					
PCL-201	S	To determine effects on seizure threshold, Effect in models of convulsion/epilepsy, Comparators: SSRIs, CT metabolites alone and with threshold dose of phenytoin	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram has a favorable side effect profile Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability	Available					Data insufficient to support publication
PCL-202	S	Acute effect of SSRIs, Sexual Behavior male rat, Comparators CT, paroxetine, fluoxetine, R-fluoxetine	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram has a favorable side effect profile	Available			Mar-01	Mar-02	Psychoneuroendocrinology

Revised March 5, 2003

Study	Type*	Description	Study Director	Key Messages	First Reveal	Abstract Due Date	Meeting/ Date	Manuscript Submission Date	Publication Date	Journal/Comments
				Escitalopram has a favorable side effect profile Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability						
PCL-208	S	Sexual dysfunction/ejaculatory delay, Effects on plasma oxytocin levels, rat, Comparator paroxetine	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram has a favorable side effect profile Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability	Proposed					Psychoneuroendocrinology
PCL-209	S	Sedation/somnolence, Ethanol/benzodiazepine induced sleep time, rotarod guinea pig Comparator: CT, mepyramine	FRX/HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram has a favorable side effect profile Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability	Ongoing		CINP Jun-02			Poster combines data from PCL-302, 208, 320, 322, 208, 304; super selectivity in vitro and in vivo
							ECNP Oct-02			Poster combines data from PCL-302, 208, 320, 322, 208, 304; super selectivity in vitro and in vivo
PCL-210	S	GI function, Gastrointestinal motility and secretion, rat, Comparator paroxetine	FRX/HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram has a favorable side effect profile Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability	Proposed					
PCL-211	S	Female sexual dysfunction, Effects on blood flow to vagina and clitoris and NOS activity in rabbits, Saenz de Tejada, Comparator paroxetine	FRX/HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram has a favorable side effect profile Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability			ECNP Oct-02			
						Oct-02	SoBP May-03			
	S	Libido, Female sexual behavior, lordosis, Comparator, paroxetine	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs	Proposed					

Study	Type*	Description	Study Director	Key Messages	Final Report	Abstract Due Date	Meeting/ Date	Manuscript Submission Date	Publication Date	Journal/Comments
				Escitalopram has a favorable side effect profile						
				Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability						
	S	Discontinuation Study, Comparator paroxetine	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram has a favorable side effect profile Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability	Proposed					
PCL-301	MA	Hypophagia Mechanistic model for increase 5-HT output in rats Effect measure is decreases intake of chocolate milk, Comparators CT, RCT, R-fluoxetine	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is the active isomer of citalopram in terms of antidepressant/anxiolytic effect Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability	Available					
PCL-302	MA	1-5-HTP potentiation in mice and rats Comparators CT	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is the active isomer of citalopram in terms of antidepressant/anxiolytic effect Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability	Available			Jul-01		Journal TBD manuscript combines data from PCL-001, PCL-002, PCL-003, PCL-101, PCL-103, PCL-107, PCL-302, and in vitro uptake inhibition
							ECNP Sep-99			poster presents mouse data combined with PCL-101
							SCBP May-00			
							NCDEU Jun-00			
							CINP Jul-00			
							Forum on Mood & Anxiety Disorders Nov-01			Poster combines data from PCL-302, 208, 320, 322, 209, 304, super selectivity in vitro and in vivo
							SCNP Apr-01			poster presents cat data combined with PCL-331

Study	Type*	Description	Study Director	Key Messages	Final Report	Abstract Due Date	Meeting/ Date	Manuscript Submission Date	Publication Date	Journal/Comments
							SCNP Apr-02			Poster combines data from PCL-302, 208, super selectivity in vivo
							CINP Jun-02			Poster combines data from PCL-302, 208, 320, 322, 209, 304, super selectivity in vitro and in vivo
							WCP (WFA) Aug-02			Poster combines data from PCL-302, 208, super selectivity in vivo
							ECNP Oct-02			Poster combines data from PCL-302, 208, 320, 322, 209, 304; super selectivity in vitro and in vivo
PCL-303 In vitro	MA	Binding of 3H-S-CT, 3H-RCT and 3H-R/S-CT to serotonin transporter in rat brain	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is the active isomer of citalopram in terms of antidepressant/anxiolytic effect Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability	Available		ACNP Dec-00			poster combines data from PCL-001, PCL-002, PCL-303 2nd poster combines data from PCL-102, PCL-103, PCL-303
							SOBP May-01			poster combines data from PCL-102, PCL-103, PCL-303
							APA May-01			poster combines data from PCL-001, PCL-002, PCL-303
							NCDEU May-01			poster combines data from PCL-001, PCL-002, PCL-303
							WCBP Jul-01			poster combines data from PCL-001, PCL-002, PCL-303
PCL-304 In vitro	MA	Effect S- and R- citalopram on monoamine transporter binding and function Also determine affinity for alpha1, M1, H1, 5-HT2C receptors, Owens, Comparators fluoxetine, R-fluoxetine, fluvoxamine, sertraline, paroxetine, CT	FRK	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is the active isomer of citalopram in terms of antidepressant/anxiolytic effect Escitalopram has a favorable side effect profile Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability	Available			Sep-00	Published Sep-01	Owens et al Biol Psychiatry 2001;50 345-350
							APA May-00			
							NCDEU Jun-00			
							CINP Jul-00			
							Neuro-science Nov-00			
							Forum on Mood & Anxiety Disorders Nov-01			Poster combines data from PCL-302, 208, 320, 322, 209, 304, super selectivity in vitro and in vivo
							SCNP Apr-01			
							SCNP Apr-02			Poster combines data from PCL-304, 322,320, super selectivity in vivo
							CINP Jun-02			Poster combines data from PCL-302, 208, 320, 322, 209, 304; super selectivity in vitro and in vivo

Study	Type*	Description	Study Director	Key Messages	Final Report	Abstract Due Date	Meeting/ Date	Manuscript Submission Date	Publication Date	Journal/Comments
							WCP (WPA) Aug-02			Poster combines data from PCL-304, 322,320, super selectivity in vitro
							ECNP Oct-02			Poster combines data from PCL-302, 206, 320, 322, 209, 304, super selectivity in vitro and in vivo
PCL-305 in vitro	MA	Effect S-CT & RCT on rat monoamine transporter binding and function, Comparators SSRIs, venlafaxine, reboxetine	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is the active isomer of citalopram in terms of antidepressant/anxiolytic effect Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer	Available					Data insufficient to stand alone, combine with data from depression model and/or anxiety model
				Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability						
PCL-306 in vitro	MA	5-HT release in synaptosome Assessment of 5-HT releasing properties of S-enantiomer in rat brain synaptosomes, Comparators CT, fenfluramine	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is the active isomer of citalopram in terms of antidepressant/anxiolytic effect Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability	Available					Data insufficient to stand alone, can be combined with other data
PCL-307 in vitro	MA	5-HT transport and electrophysiology in oocytes 1) Studies of 5-HT uptake inhibitory properties of S-,R- and R,S-citalopram in oocytes expressing h5-HTT 2) Studies of effect of S-,R- and R,S-citalopram on ion current properties of h5-HTT, Wiberg Aarhus	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is the active isomer of citalopram in terms of antidepressant/anxiolytic effect Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability	Ongoing Q2-00	 Mar-03	 ECNP Oct-02 ECNP Sep-03	Oct-01		Data insufficient to stand alone, can be combined with PCL-310 and PCL-311 Journal TBD
PCL-308 in vitro	MA	Binding of 3H-S-CT to human 5-HT transporter and its displacement by RCT, Mike Owens	FRK	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is the active isomer of citalopram in terms of antidepressant/anxiolytic effect Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability	Ongoing			Oct-01		Data insufficient to stand alone, can be combined with PCL-310 and PCL-311 Journal TBD

Study	Type*	Description	Study Director	Key Messages	Final Report	Abstract Due Date	Meeting/ Date	Manuscript Submission Date	Publication Date	Journal/Comments
PCL-309 In vivo	MA	Effect on 5-HT-1A receptor mediated inward rectifying potassium current in DRN, rat CT, fluoxetine, D Bayliss	FRX	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is the active isomer of citalopram in terms of antidepressant/anxiolytic effect Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability	Planned					Data insufficient to stand alone, can be combined with PCL-310 and PCL-311
PCL-310 In vivo	MA	Microdialysis study in rat cortex to measure 5-HT and DA after chronic treatment, Sertraline, Comparators CT, RCT	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs	Ongoing			Oct-01		Wait to publish until EU approval Journal TBD
				Escitalopram is the active isomer of citalopram in terms of antidepressant/anxiolytic effect			CINP Jun-02			pharmacology review poster will include microdialysis data
				Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer			WCP (WPA) Aug-02			poster combines data from PCL-310, PCL-311, PCL-319
				Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability			ECNP Oct-02			poster combines data from PCL-310, PCL-311, PCL-319
							IFMAD Nov-02			poster combines data from PCL-310, PCL-311, PCL-319
							ACNP Dec-02			poster combines data from PCL-310, PCL-311, PCL-319
PCL-311 In vivo	MA	Microdialysis study in rat cortex to measure 5-HT after acute systemic and local treatment, Comparators CT, RCT, paroxetine	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs	Ongoing			Oct-01		Wait to publish until EU approval Journal TBD
				Escitalopram is the active isomer of citalopram in terms of antidepressant/anxiolytic effect			CINP Jun-02			pharmacology review poster will include microdialysis data
				Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer			WCP (WPA) Aug-02			poster combines data from PCL-310, PCL-311, PCL-319
				Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability			ECNP Oct-02			poster combines data from PCL-310, PCL-311, PCL-319
							IFMAD Nov-02			poster combines data from PCL-310, PCL-311, PCL-319
							ACNP Dec-02			poster combines data from PCL-310, PCL-311, PCL-319
PCL-313 In vivo	MA	SPECT/PET imaging of 5-HTT in monkeys, Citalopram Kds, Comparators CT, RCT	FRX	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is the active isomer of citalopram in terms of antidepressant/anxiolytic effect Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer	Proposed					

Revised March 5, 2003

Study	Type*	Description	Study Director	Key Messages	Final Report	Abstract Due Date	Meeting/ Date	Manuscript Submission Date	Publication Date	Journal/Comments
				Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability						
PCL-314 in vivo	MA	Effect on D2 receptor binding and expression in chronic mild stress model, Uses tissue from PCL-014, Baldessarini	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is the active isomer of citalopram in terms of antidepressant/anxiolytic effect Escitalopram has a faster onset of antidepressant action	Proposed					
PCL-315 in vivo	MA	Determination of S- and R-citalopram and CT concentration in the brain	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs	Available			Oct-01		Data insufficient to stand alone, can be combined with PCL-310 and PCL-311 Journal TBD
				Escitalopram is the active isomer of citalopram in terms of antidepressant/anxiolytic effect						
PCL-316 in vivo	MA	Effect on dorsal raphe neuron firing rate after chronic treatment, rats, Lotta Aberrotes, Comparators R-fluoxetine, CT, paroxetine	FRX	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is the active isomer of citalopram in terms of antidepressant/anxiolytic effect Escitalopram has a faster onset of antidepressant action Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability	Ongoing					
PCL-317 ex vivo	MA	Effects of S-, R- and racemic citalopram on 5 HT, NA, and DA uptake by brain synaptosomes and/or platelets to determine relative contribution of S- and R-enantiomers to citalopram's effects on 5-HT transport, J Reusch, Comparators CT, data on other SSRIs on file	FRX	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is the active isomer of citalopram in terms of antidepressant/anxiolytic effect Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability	Ongoing?					Data insufficient to stand alone
PCL-318	MA	h5-HTT mutations, affinity and uptake inhibition Studies of S-,R- and R,S-citalopram in h5-HTT mutants expressed in insect cells Affinity and 5-HT uptake inhibition Investigator has been informed on confidentiality and publication limitations Comparators CT, RCT	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is the active isomer of citalopram in terms of antidepressant/anxiolytic effect	Planned					Data insufficient to stand alone

Study	Type*	Description	Study Director	Key Messages	First Report	Abstract Due Date	Meeting/ Date	Manuscript Submission Date	Publication Date	Journal/Comments
				Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability						
PCL-319	MA	Binding studies assessing for allosteric properties of enantiomers, Comparators: CT, RCT	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is the active isomer of citalopram in terms of antidepressant/anxiolytic effect Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability	Available			Oct-01		Data insufficient to stand alone, can be combined with PCL-310 and PCL-311 Journal TBD
							WCP (WPA) Aug-02			Poster combines data from PCL-310, 311, 319
							ECNP Oct-02			poster combines data from PCL-310, PCL-311, PCL-319
							IFMAD Nov-02			poster combines data from PCL-310, PCL-311, PCL-319
							ACNP Dec-02			poster combines data from PCL-310, PCL-311, PCL-319
PCL-320	MA	In vitro receptor profile, Comparators: R-fluoxetine, paroxetine, sertraline, venlafaxine, mirtazapine, reboxetine	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability			SCNP Apr-02			Poster combines data from PCL-304, 322,320, super selectivity in vitro
							Forum on Mood & Anxiety Disorders Nov-01			Poster combines data from PCL-302, 208, 320, 322, 209, 304; super selectivity in vitro and in vivo
							WCP (WPA) Aug-02			Poster combines data from PCL-304, 322,320, super selectivity in vitro
							ECNP Oct-02			Poster combines data from PCL-302, 208, 320, 322, 209, 304; super selectivity in vitro and in vivo
PCL-321	MA	Acute effects on DRN firing, effects on 5-HT1A receptor mediated effects, Comparators: CT, RCT	HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs Escitalopram is the active isomer of citalopram in terms of antidepressant/anxiolytic effect Escitalopram has a faster onset of antidepressant action Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability	Available		SCNP Apr-01			poster presents rat data from PCL-302 combined with PCL-321
							APA May-01			
							WCBP Jul-01			
								Oct-01		Data insufficient to stand alone, can be combined with PCL-310 and PCL-311 Journal TBD

Study	Type*	Description	Study Director	Key Messages	Final Report	Abstract Due Date	Meeting/ Date	Manuscript Submission Date	Publication Date	Journal/Comments
PCL-322	MA	In vitro receptor profile, Comparators S-CT, SDCT, SDDCT	FRX	Escitalopram represents a new more selective and/or potent generation of SSRIs	Available		Forum on Mood & Anxiety Disorders Nov-01			Poster combines data from PCL-302, 306, 320, 322, 209, 304, super selectivity in vitro and in vivo
				Escitalopram is the active isomer of citalopram in terms of antidepressant/anxiolytic effect			SCNP Apr-02			Poster combines data from PCL-304, 322,320, super selectivity in vitro
				Escitalopram has improved side effect, drug interaction and safety profiles resulting from the removal of the inactive moiety, the R-enantiomer			CINP Jun-02			Poster combines data from PCL-302, 306, 320, 322, 209, 304, super selectivity in vitro and in vivo
				Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability			WCP (WPA) Aug--02			Poster combines data from PCL-304, 322,320, super selectivity in vitro
							ECNP Oct-02			Poster combines data from PCL-302, 306, 320, 322, 209, 304, super selectivity in vitro and in vivo
PCL-323 ex vivo	MA	Effects of S-CT on 5-HT uptake in brain synaptosomes after chronic oral treatment	FRX/HLu	Escitalopram represents a new more selective and/or potent generation of SSRIs			WCP (WPA) Aug-02			
				Escitalopram is the active isomer of citalopram in terms of antidepressant/anxiolytic effect			ECNP Oct-02			Poster combines data from PCL-001, 003, 101, 103, 323 SSRIs in anxiety, depression, aggression
				Escitalopram is a refinement of citalopram in terms of antidepressant effect and tolerability						
	MA	Ketamine affects binding of S-CT to 5-HT reuptake site	HLu		Available		SNM Jun-01			

Key* Type
PK - Pharmacokinetics
PD - Pharmacodynamics
D - Depression
A - Anxiety (PD, GAD, SAD)
S - Side Effects
MA - Mechanism of Action

Appendix III

APPENDIX IV

PROFESSIONAL MEETING AND SYMPOSIA PLAN

A. PSYCHIATRY

Society of Biological Psychiatry (SOBP):

- 5/15/03 - 5/17/03 in San Francisco, CA
- Expected attendance of 600

American Psychiatric Association (APA):

- 5/17/03- 5/22/03 in San Francisco, CA
- Expected attendance of 18,000

New Clinical Drug-Evaluation Unit Program (NCDEU):

- 5/27/03 – 5/30/03 in Boca Raton, FL
- Expected attendance of 1,000

Collegium Internationale Neuro-Psychopharmacologicum (CINP):

- 10/12/03 – 10/15/03 in Beijing, China
- Expected attendance of 5,000

World Psychiatric Association/World Congress of Psychiatry (WPA/WCP)

- 9/10/03 - 9/15/03 in Cairo, Egypt

American Psychiatric Association Institute on Psychiatric Service (APA-I)

- 10/29/03 – 11/02/03 in Boston, MA
- Expected attendance of 2,000

U.S. Psychiatric Congress

- 11/6/03 – 11/9/03 in Orlando, FL
- Expected attendance of 3,000

American College of Neuropsychopharmacology (ACNP)

- 12/7/03 – 12/11/03 in Puerto Rico
- Expected attendance of 1,300

International Congress of Geriatric Psychoneuropharmacology (ICGP)

- 12/12/03 – 12/14/03 in Puerto Rico

American Association for Geriatric Psychiatry (AAGP)

- 3/12/04 – 3/15/04 in Baltimore, MD
- Expected attendance of 1,200

Anxiety Disorders Association of America (ADAA)

- 3/04
- Expected attendance of 650

PriMed Psychiatry Updates

- Fall 03
- Miami, New York, Chicago, Washington, DC, San Francisco, Los Angeles

B. PRIMARY CARE

American Academy of Family Physicians (AAFP)

- 10/1/02 – 10/5/03 in New Orleans, LA
- Expected attendance of 20,000

American College of Obstetricians and Gynecologists (ACOG)

- 4/26/03 – 4/30/03 in New Orleans, LA
- Expected attendance of 5,000

U.S. Geriatrics and Long Term Care Congress

- 6/19/03 – 6/21/03 in San Francisco, CA
- Expected attendance of 2,000

American College of Physicians-American Society of Internal Medicine (ACP)

- 4/3/03 – 4/5/03
- Expected attendance of 10,000

American Geriatrics Society (AGS)

- 5/14/03 – 5/14/03 in Washington, DC
- Expected attendance of 2,000

Pri-Med Regional Meetings

- Mid-West: 6/19/03 – 6/21/03 in Chicago, IL
- East: 11/7/03 – 11/9/03 in Boston, MA
- Expected attendance of 5,000 at both

C. OTHER ALLIED HEALTH PROFESSIONS

Academy of Managed Care Pharmacy (AMCP)

- 4/19/04 – 4/12/03 in Minneapolis, MN and 11/10/03 – 11/15/03 in Pasadena, CA
- Expected attendance of 4,000

American Medical Directors Association (AMDA)

- 3/4/04 – 3/7/04 in Phoenix, AZ
- Expected attendance of 2,000

American Society of Consultant Pharmacists (ASCP)

- 5/14/03 – 5/16/03 in Tampa Florida and 11/12/03 – 11/14/03 in San Antonio, TX
- Expected attendance of 4,000

APPENDIX V

LEXAPRO PHASE IV CLINICAL STUDIES

LXP-1	1	A Prospective Single Site, Open Label Study of the Safety and Efficacy of [illegible] in the Treatment of [illegible] Depression and Diabetes Mellitus	Amsterdam, Jay/ U Penn	[illegible]	drug request [illegible]	36	$ 99,[illegible]	$ 6,341.18	Y	Y	Y	contract executed 11/13/02	2/04			0%	$24,971.90	25%	Drug requested 3/18/03	2004 APA NCDEU		Spring 2005
LXP-2	5	Esc & Risperidone in the Tx of Psychotic Depression	DeBattista, Charles/ Stanford	[illegible]	drug request 3/18/03	80	$ 46,500.00	$ 6,650.00	Y	Y	Y	contract executed 11/18/02	2/04	1/28/2003		0%	$16,625.00	25%	Drug Shipped	2004 APA NCDEU		Spring 2005
LXP-3	4	Esc in Body Dysmorphic Disorder	Phillips, Katharine/ Butler Hospital	Whitlock	drug requested 1/22/03	15	$ 63,230.00	$ 4,318.00	Y	Y	Y	contract executed 3/17/03	2/04			0%	$17,071.88	27%	drug requested 3/20/03	2004 APA NCDEU		Spring 2005
LXP-4	8	Esc for [illegible] in adults	Ketter, Terence/ Stanford	[illegible]		24	$110,000.00	$ 4,583.33	Y	Y	Y	contract executed 1/23/03	2/04	10/15/2002	11	46%	$55,000.00	50%	Under 50% Enrolled	2004 APA NCDEU		Spring 2005
LXP-5	12	Esc Tx for male subjects with PTSD	Neylan, Thomas/ UCSF	[illegible]	drug request 12/4/02	16	$ 96,000.00	$ 6,000.00	Y	Y	Y	contract executed 7/9/02	2/04	1/7/2003	4	25%	$24,000.00	25%	Under 50% Enrolled	2004 APA NCDEU		Spring 2005
LXP-6	13	Escitalopram for Major Depression in Perimenopausal Women	Freeman, Marlene/ U of AZ	[illegible]	drug request 3/13/03	20	$ 81,320.00	$ 4,066.00	Y	Y	Y	contract executed 10/08/02	2/04	2/3/2003		0%	$20,330.00	25%	Drug Shipped	2004 APA NCDEU		Spring 2005
LXP-7	14	Combination Treatment of Major Depression and Comorbid Social Anxiety Disorder	Schneier, Franklin/ NYS Psych Institute	[illegible]		20	$ 85,919.00	$ 4,295.95	Y	Y	Y	contract executed 5/31/02	2/04	10/17/2002	5	25%	$42,959.50	50%	Under 50% Enrolled	2004 APA NCDEU		Winter 2004
LXP-8	16	Esc in Specific Phobia	Connor, Kathryn/ Duke Univ	[illegible]	need reg docs and drug form	12	$110,750.00	$ 9,479.17	Y	Y		contract executed 2/20/03	2/04			0%	$27,875.00	25%	contract executed	2004 APA NCDEU		Spring 2005
LXP-9	18	Efficacy of Esc in the Tx of Internet Addiction	Hollander, Eric/ Mt Sinai School of Med	[illegible]	drug request 12/20/02	15	$ 54,469.00	$ 3,631.27	Y	Y	Y	contract executed 11/21/02	9/03			0%	$13,617.25	25%	drug requested 12/20/02	2004 APA NCDEU		Winter 2004
LXP-10	19	Open Label Flexible Dose Randomized 12-Week Clinical Trial of the Safety and Efficacy of Escitalopram in the Treatment of PTSD	Baker, Dewleen/ Cincinnati VA Med Center	[illegible]	ongoing	[illegible]	$106,875.00	$ 1,562.50	Y	Y	Y	contract executed 7/10/02	4/04	10/9/2002	8	27%	$26,718.75	25%	Under 50% Enrolled	2004 AAFP		Spring 2005

Confidential

FCA0017862

LXP-24	55	The Safety and Efficacy of Escitalopram in Treatment of Depression Following Acute Myocardial Infarction	Madhukar Trivedi/ University of Texas Southwestern Medical Center	Eggert		22	$99,487.00	$4,531.21	Y	Y									Pending Tier 2	2004 ACNP		Fall 2005
LXP-26	70	A Randomized, Double-Blind, Placebo Controlled Trial of Escitalopram on Pathological Gambling	Wayne K Goodman/ University of Florida	Wagner	drug shipment requested	44	$70,545.00	$ 1,807.84	Y	Y	Y	contract executed 10/1/02	2/04	1/9/2003		0%	$19,886.25	25%	Drug Shipped	2004 APA NCDEU		Spring 2005
LXP-29	64	Efficacy of Escitalopram on High Anxiety Geriatric Depression	Lawrence J Albers/ Long Beach VA Health Care Center	Gilbert	drug request 12/04/02	10	$77,220.00	$ 2,174.00	Y	Y	Y	contract executed 11/18/02	2/04	1/8/2003	1	1%	$19,305.00	25%	Under 50% Enrolled	2004 APA NCDEU		Winter 2004
LXP-30	43	An Open-Label Trial of Escitalopram for Major Depression in Hepatitis C	Ondria C Gleason, MD/ The University of Oklahoma	Lopez	ongoing	20	$81,120.00	$ 4,016.00	Y	Y	Y	contract executed 6/24/02	2/04	10/8/2002	12	60%	$40,560.00	50%	Over 50% Enrolled	2004 APA NCDEU		Winter 2004
LXP-31	67	Escitalopram in the Treatment of Social Phobia in College Students A Pilot Study	Radu V Saveanu/ Ohio State University Medical Center	Ruby	need reg docs and drug form	20	$64,680.00	$ 1,234.00	Y	Y	Y	sent for signature 6/18/02	2/04			0%		0%	In Contracting	2004 APA NCDEU ADAA		Spring 2005
LXP-32	91	Pharmacotherapy of Traumatic Grief A Pilot Study	M Katherine Shear & Bruce Pollock	Pensinger	need reg docs and drug form	24	########	$ 3,174.54	Y	Y	Y	contract executed 11/4/02	2/04			0%	$11,090.10	21%	In Contracting	2004 APA NCDEU		Spring 2005
LXP-33	50	A 12-Week, Open-Label Trial of Escitalopram for the Treatment of Bereavement Depression	Paula L Hensley/ University of New Mexico Department of Psychiatry	Vander Zanden	need reg docs and drug form	10	$99,980.00	$ 1,332.67	Y	Y	Y	contract executed 2/10/03	2/04			0%	$24,995.00	25%	In Contracting	2004 APA NCDEU		Spring 2005
LXP-34	94	Double-Blind Placebo Controlled Study of Escitalopram in the Treatment of Dysthymic Disorder	David Hellerstein/ NYS Psych Institute	Baranpanne	drug request 12/4/02	16	$97,131.00	$ 2,698.08	Y	Y	Y	executed 10/16/02	summer 2004	1/28/2003		0%	$24,282.75	25%	Drug Shipped	2004 ACNP		Spring 2005
LXP-35	99	Optimal TX for Childhood Anxiety Under a NIMH Center Grant	Mark Riddle/ John Hopkins University	Ulmschneider	change during negotiation in ESC parameters start date 12/03 pending NIH approval	50	$28,390.00	$567.80	Y	Y			12/04						Pending Tier 2	2004 ACNP		Fall 2005
LXP-36	83	Escitalopram for the Treatment of Self-Injurious Skin Picking	Nancy Keuthen, Darin Dougherty, Kerry Wong/Massachusetts General Hospital	Levanseler	drug was requested on 11/26/02	10	$87,500.00	$ 2,916.67	Y	Y	Y	contract executed 9/16/02	2/04	1/9/2003		0%	$21,875.00	25%	Drug Shipped	2004 APA NCDEU		Spring 2005
LXP-37	47	Effects of Escitalopram on Respiratory Response to CO2 Inhalation in Subjects at High Risk for Panic Disorder	William Coryell/ University of Iowa College of Medicine	Lopez	drug request 1/6/03	40	$98,175.00	$ 2,439.38	Y	Y	Y	Contract executed 11/15/02	2/04	1/28/2003		0%	$24,793.75	25%	Drug Shipped	2004 APA NCDEU ADAA		Spring 2005

LXP-38	117	Open-Label, Flexible Dose, 12-Week Clinical Trial of the Safety and Efficacy of Escitalopram in the Treatment of Comorbid Anxiety and Depression in the Elderly	Somaia Mohamed/ Department of Veterans Affairs medical Center	Ruby	drug request 11/13/02	30	$42,720.00	$ 2,134.80	Y	Y	Y	contract executed 9/19/02	2/04	11/14/2002	3	15%	$10,680.00	25%	Under 50% Enrolled	2004 APA NCDEU AAGP AGS		Spring 2005
LXP-39	114	An Open-Label Study of Escitalopram in the Treatment of Atypical Depression	Erik B. Nelson/ University of Cincinnati College of Medicine	Ruby	drug request 12/4/02	30	$49,750.00	$ 2,487.50	Y	Y	Y	contract executed 9/20/02	2/04	1/9/2003	4	30%	$12,437.50	25%	Under 50% Enrolled	2004 APA NCDEU		Spring 2005
LXP-40	115	An Open-Label Study of Escitalopram for the treatment of depression of Alzheimer's Disease	Constantine G. Lyketsos/ Johns Hopkins Hospital	Ulmschneider	need reg docs	15	##########	$ 9,945.80	Y	Y		sent for execution 2/4/03	2/04			0%	$12,296.75	25%	In Contracting	2004 APA NCDEU AAGP AGS		Spring 2005
LXP-41	73	Escitalopram in the Treatment of Hypochondriasis in Major Depression	Jonathan S. Abramowitz/ Mayo Clinic	Marino	need reg docs and drug form	17	$61,836.00	$ 1,678.59	Y	Y	Y	contract executed 2/14/03	2/04			0%	$15,889.00	25%	In Contracting	2004 APA NCDEU		Spring 2005
LXP-42	80	A Pilot Twelve Week Double-Blind, Randomized Trial of Escitalopram and Risperidone for the Behavioral Disturbances of Alzheimer's Disease in Long-Term Care Settings	Ashok J. Bharucha/ Western Psychiatric Institute and Clinic	Pennister	need reg docs and drug form	30	##########	$ 6,343.71	Y	Y	Y	sent for execution 3/27/03	2/04			0%	$12,718.75	25%	In Contracting	2004 APA NCDEU AAGP AGS		Winter 2004
LXP-43	54	Escitalopram in the Treatment of Patients with Agitated Dementia	Adrian Leibovici/ University of Rochester Medical Center	Pennister	need reg docs and drug form	20	$99,660.00	$ 4,983.00	Y	Y	Y	contract executed 4/3/03	2/04			0%	$24,915.00	25%	contract executed	2004 APA NCDEU AAGP AGS		Spring 2005
LXP-44	83	Efficacy of Escitalopram (as a Monotherapy or Augmenting Strategy) for the Treatment of Depression in Menopausal Women	Lee S. Cohen/ Massachusetts General Hospital, Harvard Medical School	Levasseur	requested drug 2/26/03	30	$149,463.00	$4,982.10	Y	Y	Y	contract executed 1/28/03	2/04	3/3/2003	8	27%	$29,892.00	20%	Drug Shipped	2004 APA NCDEU		Spring 2005
LXP-45	95	Escitalopram for the Treatment of Post Stroke Pathological Crying	Barnett Meyers/ Weill Medical College of Cornell university	Whitlock	need reg docs	40	$67,320.00	$1,683.00	Y	Y	Y	contract executed 3/27/03	summer/ fall 2004			0%	$21,330.00	12%	contract executed	summer/fall 2004 / ACNP 2004		Fall 2005
LXP-46	103	Escitalopram in the Treatment of Intrusive Thoughts in Patients with OCD	Cheryl N. Carmin/ University of Illinois Chicago	Marino	need reg docs and drug form	12	$62,275.00	$3,109.50	Y	Y	Y	Contract executed 1/17/03	2/04			0%	$15,568.75	25%	Contract Executed	2004 APA NCDEU		Spring 2005

LXP-47	113	Escitalopram in the Treatment of Generalized Anxiety Disorder with Comorbid Depression	Narah Patrick Emmanuel/ Medical University of South Carolina	Stilson	drug request sent 3/27/03	15	$82,621.00	$5,105.31	Y	Y	Y	contract executed 11/29/02	2/04	4/2/2003		09	$20,616.21	25%	Drug Shipped	2004 APA NCDEU ADAA		Spring 2005
LXP-48	116	Escitalopram in the Treatment of Trichotillomania	Kishore M Gadde/ Duke Hospital	Bitner	need reg docs and drug form	20	$92,210.00	$4,612.50	Y	Y	Y	contract executed 1/29/03	2/04			09	$21,062.50	25%	contract executed			Spring 2005
LXP-49	123	An Open-Label Evaluation of the Safety and Efficacy of Escitalopram in Children and Adolescents with Depression	Karen Wagner/ UTMB	Eggers	ongoing	12	$98,190.00	$8,212.50	Y	Y	Y	contract executed 9/26/02	1/03	10/9/2002	*	6/2	$71,012.50	75%	Drug Shipped	2002 ACNP		Fall 2003
LXP-50	81	Escitalopram in the Treatment of Social Phobia in Individuals Who Stutter. A Double-Blind, Placebo Controlled Trial	Gerald A Maguire/ UC Irvine	Gilbert	drug request 3/10/03	16	$83,019.00	$5,182.49	Y	Y	Y	contract executed 3/3/03	2/04	3/26/2003		09	$49,871.50	24%	Drug Shipped	2004 APA NCDEU		Spring 2005
LXP-51	100	An Open Label Trial of Escitalopram for the Treatment of Depression in Parkinson's Disease	David Arciniegas/ Colorado Psychiatric Hospital	Vander Zanden		15	$82,661.00	$ 1,310.71	Y	Y		contract executed 12/17/02	2/04	2/3/2003		09	$20,665.00	25%	Drug Shipped	2004 APA NCDEU AACP		Spring 2005
LXP-52	107	An Open-Label, Parallel Group Study of the Safety and Efficacy of Escitalopram in the Treatment of Chronic Fatigue Syndrome With and Without Comorbid Major Depression	Giampaolo Gallo/ University of Pennsylvania School of Medicine	Ulbrich sender	need IRB reg docs and drug form	16	$99,672.00	$ 4,229.50	Y	Y		draft contract ref 10/28/02	2/04			09	$24,918.00	25%	In Contracting	2004 APA NCDEU		Spring 2005
LXP-53	119	Neurosteroid Metabolism and the Antidepressant Effects of Escitalopram	Mellon S UCSF School of Med	Karsner adds		15	$81,513.00	$ 5,434.20	Y	Y	Y	contract executed 2/13/03	2/04			03	$20,378.25	25%	drug requested 2/26/03	2004 APA NCDEU SOBP		Spring 2005
LXP-54	86	Escitalopram for the Treatment of Depression in Parkinson's Disease. A Pilot Study	Daniel Weintraub/ University of Pennsylvania	Ulbrich sender	drug request 12/3/02	20	$98,880.00	$ 4,944.00	Y	Y	Y	contract executed 11/22/02	2/04	1/28/2003		03	$24,720.00	25%	Drug Shipped	2004 APA NCDEU AACP		Spring 2005
LXP 55	100	Vascular Depression and Magnetic Stimulation Therapy	Robert G Robinson/ University of Iowa College of Medicine	Lopez	need reg docs and drug form	149	drug only	drug only	Y	Y	Y	sent for execution 3/18/03							In Contracting			

Confidential

FCA0017866

[illegible]																						
	60	An Open Label Trial of Escitalopram in the Treatment of Women with Chronic Pelvic Pain	Candace S Brown/ University of Tennessee Health Science Center	Reese	hold off to review until phase IIIb plans are known	15	$76,820.00	$5,121.33														
	28	Escitalopram and Psychoeducation for Childhood Social Phobia	Murray Stein/UCSD	Gilbert	need itemized budget	124	$675,000.00	$5,443.55											Pending			
	33	Pilot Study to Evaluate Escitalopram in Obsessive Compulsive Disorder	Jonathan Davidson/ Duke University Medical Center	Reese	would prefer a somatic symptom study																	
	62	A Randomized, Placebo-Controlled Study of Escitalopram for the Treatment of Hot Flashes in Breast Cancer Survivors.	Christina Pozo-Kaderman/ Mt Sinai Comprehensive Cancer Center	Wagner	change dosing, study duration and population [illegible]	50	$81,125.00	$1,622.50											Pending			
	68	Escitalopram in the Treatment of Depressive Symptoms in Breast Cancer Patients	Joel L. Dimsdale/ UC San Diego	Callaway	need protocol																	
	79	Pharmacotherapeutic Prevention of Depression and Anxiety: a Trial of Escitalopram in Mothers of Children Recently Diagnosed with Cancer or Traumatic Brain Injury	Henry A Nasrallah/ University of Mississippi School of Medicine	Eggers	hasn't been reviewed by RSC need itemized budget	30	$190,000.00	$1,000.00														
	91	Escitalopram in the Treatment of Hot Flashes in Androgen Deprived Prostate Cancer Patients An Open-Label Study	James C Coyne/ University of Pennsylvania Medical Center	Ulmschneider	need full protocol																	

Confidential

	91	A Double-Blind Trial of Escitalopram in Patients with Borderline Personality Disorder	George Nurnberg/ University of New Mexico	Vander Zanden	need SSRI data portable educational grant	40	$160,000 00	$4,000 00											pending educational grant			
	109	Escitalopram for Negative and Depressive Symptoms of Schizophrenia	Daniel J Dugan & Roger Sommi/ UMKC School of Pharmacy	Lopez	pending protocol revisions	20	$84,625 00	$4,231 25														
	104	Lexapro in the Treatment of Recurrent Migraine and tension-type Headache	Raymond C Tait/ St Louis University School of Medicine	Lopez		20	$93,732 00	$4,686 60														
	111	A Pilot Double-Blind Study of Escitalopram for the Treatment of Type A Alcoholics	Helen Pettinati-Kyle Kampman-Charles O'Brien/	Ulbrich-sender	focus on depression rather than on abstinence	30	$99,057 00	$3,301 90											Pending Tier 2			
	120	(Multi-site study on dysthymia)	David Dunner, Mark Rapaport, Charles De Battista	Calvan	concept - need protocol, budget and CVs -revise study design, pending CF/IMP	60	$297,800 00	$4,950 00														
	126	Study to Evaluate the Efficacy of Escitalopram for Migraine Prophylaxis	Alexander Mauskop/	Aurora	need budget and full protocol	60		$0 00											Pending Tier 2			
	129	Escitalopram in the Treatment of Adult Separation Anxiety A Pilot Study	Katherine Shear/ Univ of Pittsburgh	Prentner	on hold until after her bereavement study is enrolled														On Hold			
	131	Single-Site, Double-Blind, Flexible-Dose, Placebo Controlled Study of the Efficacy, Tolerability and Safety of Escitalopram in the Treatment of Irritable Bowel Syndrome	Prakash Masand/ Duke University medical Center	Reese	possible multi-site with Dr Oldham	60	$506,250 00	$8,437 50											Pending Tier 2			

	133	An Open-Label Study of the Efficacy and Tolerability of Escitalopram for the Treatment of Minor Depression in Patients with Parkinson's Disease	Laura Marsh/ Johns Hopkins	Ulmschneider	send CV Tier 2	15	$99,940.00	$6,662.67											Pending Tier 2			
	135	Prevention of Post-Stroke Depression Treatment Strategy	Robert G Robinson/ University of Iowa College of Medicine	Lopez		201	drug only	drug only											Pending Tier 2			
	139	Escitalopram for the Treatment of Major Depression in Individuals with Mental Retardation or a Pervasive Developmental Disorder an Open-Label Study	Scott Stiefel/ University of Utah	Vander Zanden	need pilot data	30	$75,762.58	$2,523.42											Pending Tier 2			
	144	Interstitial Cystitis and Panic Disorder A Potential genetic Syndrome	Myrna Weissman/ Columbia University	Aseem		75													Hasn't been reviewed			
	146	Treatment of Early Bereavement Related Depression A Pilot Study	Katherine Shear/ Univ of Pittsburgh	Panaitzer	need protocol	14	$67,500.00	$4,821.43											Pending Tier 2			
	148	Escitalopram in Children and Adolescents with Obsessive Compulsive Disorder An Open-Label Study	Graham Emslie/UT Southwestern Medical Center	Eggert	need full protocol and itemized budget	20													Pending Tier 2			
	149	Geriatric Depression NIMH	George Alexopoulous/ NY Presbyterian	Bussmane	final sign off after Jeanne meets with TL	120	drug only	drug only											Pending Tier 2			
	153	Escitalopram for the Prevention of Depression and Neurotoxicity in HIV-Infected Patients Coinfected with Chronic Hepatitis C and Undergoing Treatment with PEG-IFN-alpha-2b plus Ribavirin	Andrew H Miller/Emory University School of Medicine	Strobbe	need full protocol, reduce budget, send reference articles	60	$150,000.00	$2,500.00											Pending Tier 2			

	116	Open-Label Trial in Pediatric OCD	Dan Geller and Mike Jenike/ Harvard University	Levasser	need full protocol and itemized budget														Pending Tier 2			
	157	Escitalopram in the Treatment of Juvenile Depression with Comorbid Anxiety	Jeff Bostic and Jefferson Prince/ Massachusetts General-Harvard Medical School	Levasser	need full protocol and itemized budget														Pending Tier 2			
	158	Escitalopram in Children and Adolescents with Generalized Anxiety Disorder: An Open-Label Study	Aileen Oandasan and Karen Wagner/UTMB	Eggert		12	TBN	TBN														
LXP-1?	59	A Double-Blind, Placebo Controlled Trial of Escitalopram and Acamprosate, Alone and in Combination, in Outpatients with Alcohol Dependence	Barbara J Mason/ University of Miami School of Medicine	Wagner	delay until Lipha agrees to contract	200	drug only	drug only	Y	Y			2/04						Pending Tier 1	2004 APA NCDEU		Winter 2004
	159	An Open Label Flexible Dose Clinical Trial of the Short-Term Safety and Efficacy of Escitalopram in Treatment Naive and Treatment Refractory Geriatric Depression	Raymond C Tait/ St. Louis University School of Medicine	Lopez	treatment naive population, cap age levels, need pilot data	20	$99,695.00	$4,984.75											Pending Tier 2			
	160	Lexapro for the Treatment of Hot Flashes in Non-Depressed, Menopausal Women with No History of Cancer	Matthew Marcus and Roseanne DeFronzo/Robert Wood Johnson Medical School	Penalver	extend to 8 weeks, flex dosing	25	$75,000.00	$3,000.00											Pending Tier 2			

Confidential

	164	The Use of Lexapro to Prevent Post Traumatic Stress Disorder in Medical patients Impact on Symptom Severity, Medical Care Utilization, Quality of Life and Work Impairment	Mark Pollack/ Mass general	Levensever	define trauma category, lower N, lower budget	60														Pending Tier 2			
	165	Decrease in Caudate Glutaminergic Concentrations in pediatric Obsessive Compulsive Disorder Patients Treated with Escitalopram	John March/ Duke University	Reese	need protocol and budget	12	\$72,000.00	\$6,000.00												Hasn't been reviewed			
	166	The Effect of Escitalopram on the Quality of Life of Depressed and Anxious Patients with Crohn's Disease A Placebo-Controlled Pilot Study	Indu Varia/ Duke University	Reese	flex dose, increase N	12	\$97,580.00	\$8,131.67												Pending Tier 2			
	167	CBASP Augmentation for Treatment of Chronic Depression	Madhukar Trivedi/ Univ Texas SW medical center	Eggert	pending marketing	909														Hasn't been reviewed			
	171	Escitalopram in the Treatment of generalized Anxiety Disorder in Elderly Veterans	Olga Mintzer/ MUSC	Reese	pare down to phase IV parameters	195														Pending Tier 2			
	172	Escitalopram for the Treatment of Comorbid Depression and Alcohol Dependence	Therese Killen/ MUSC	Reese	held for acamprosate discussion	20	\$100,000.00	\$5,000.00												Hasn't been reviewed			
	173	An Open-Label Study of Escitalopram for the Treatment of Depression of Traumatic Brain Injury	Vani Rao/ Johns hopkins	Ulmschneider	need budget	15	\$99,330.00	\$6,622.00												Hasn't been reviewed			

	174	Escitalopram to Prevent or Ameliorate Trauma-related Psychological Disorders	Nathan Shapira/ University of Florida Brain Institute	Wagner	need budget														Hasn't been reviewed			
	175	Depression: The Search for Treatment Relevant Phenotypes	Ellen Frank/ Western Psychiatric Institute	Peneltzer		130	$1,336,433.00	$10,280.25											Hasn't been reviewed			
	176	Escitalopram Treatment of Post-partum Depression	Lilian Gonsalves & Donald Malone/ Cleveland Clinic Foundation	Ruby	taking over Parlow's study	20	$96,040.00	$4,802.00											Hasn't been reviewed			
	177	Open-Label, Flexible-Dose, 12-Week Clinical Trial of the Safety and Efficacy of Escitalopram in Adolescent Social Anxiety Disorder	John Greist/ University of Wisconsin	Martin		20													Hasn't been reviewed			
	178	An 8-Week, Outpatient, Add-On, Pilot Study of Escitalopram Oxalate 10mg in Patients with Schizophrenia	Carlos Santana/ USF	Wagner		20	$110,626.00	$5,531.30											Hasn't been reviewed			
	179	Open-Label, Variable Dose Escitalopram in the Treatment of Patients with postpartum Major Depression: A Pilot Study	Linda Chaudron/ University of Rochester	Peneltzer		25-30	$95,000.00												Hasn't been reviewed			

APPENDIX VII

PROFESSIONAL ASSOCIATIONS OF PRIORITY

AMERICAN PSYCHIATRIC ASSOCIATION

The American Psychiatric Association (APA) is recognized worldwide as the premier psychiatric society. Its 44,000 U.S. and international physicians specialize in the diagnosis and treatment of mental and emotional illnesses and substance use disorders.

In FY03 Forest Professional Relations provided an unrestricted grant and technical support to create collaboration between APA, AAFP and ACP to develop "reasonable practice" guidelines for the management of chronic depression in primary care practice. The clinical objective is to improve the percent of patients who adhere to the full duration of therapy. The first step, identifying a Standard of Care evaluation instrument, was completed in October 2002.

In 2003 the Workgroup will determine a Standard of Care Intervention Strategy and identify the instructional materials needed to implement the strategy in office setting. The strategy will be tested in each organization's Practice Research Network to validate its ability to improve adherence and prolong duration of therapy. The Workgroup seeks to publish the results of each step in a peer-reviewed Primary Care Journal to begin dissemination of the reasonable practice guidelines.

At the State level, APA Chapters engage in significant lobbying of State Health Departments to maintain mental health care budgets, including support for open Medicaid drug formularies. Forest has expanded its involvement with APA in this regard, creating an information collaboration to assist mutual efforts at the State policy level.

AMERICAN ASSOCIATION OF GERIATRIC PSYCHIATRY

The American Association of Geriatric Psychiatry (AAGP) represents and serves the field of geriatric psychiatry. The mission of AAGP is to enhance the knowledge base and standard of practice in geriatric psychiatry through education and research and to advocate for meeting the mental health needs of older Americans.

In 2002/03 AAGP is developing, for the first time, evidence-based Practice Guidelines for Late Life Depression. Publication is expected in 4Q03. An instructional "toolkit" to assist guideline implementation and an updated depression slide kit will also be issued. Forest Professional Relations is the sole support of these projects, providing an unrestricted grant and technical support.

AMERICAN COLLEGE OF NEUROPSYCHOPHARMACOLOGY

The American College of Neuropsychopharmacology (ACNP) is an elite, research-oriented professional organization with limited membership of 600 nationally recognized scienusts. Members are elected based on their original research contributions to the field of neuropsychopharmacology, representing behavioral pharmacology, brain imaging, clinical psycho-pharmacology, epidemiology, genetics, neurology, neurophysiology, psychiatry and psychology.

The principal functions of the College are research and education in mental health, including substance abuse. ACNP provides investigators the opportunity for cross-disciplinary communication at scientific meetings, and promotes a multi-discipline approach to research in the pharmacology of brain and behavior.

Forest is a major contributor to ACNP annual programming, and is a founding sponsor of it's newly created International College of Geriatric Psychopharmacology (ICGP).

AMERICAN ACADEMY OF FAMILY PHYSICIANS

The American Academy of Family Physicians (AAFP) is one of the largest national medical organizations, with more than 93,000 members. The Academy has a strong educational and policy platform, representing comprehensive primary care to patients and their families. AAFP has a rich catalog of marketing opportunities and communication vehicles to their members and their patients.

Forest has been a Corporate President's Circle Sponsor of AAFP since 2001, which provides additional marketing opportunities. Forest is also a major sponsor of the Academy's Doctors wit - Heart philanthropic program.

In conjunction with physician specialty groups (e.g. APA) AAFP develops evidence-based practice guidelines, which must be ratified by their Board of Directors at the Annual Scientific Session. AAFP is actively participating in the Forest-led collaboration with APA to develop reasonable practice guidelines for managing chronic depression in the Primary Care Physician office-setting.

Forest is actively participating in the AAFP's Annual Clinical Focus: "Caring for the Aging in America," a year-long comprehensive educational program (October 2003 – 2004). The objective is to increase the Family Physician's ability to identify and effectively manage health conditions in the elderly. Late Life Depression and Alzheimer's Dementia are key elements of this comprehensive educational program.

AMERICAN COLLEGE OF PHYSICIANS

[PREVIOUS NAME: AMERICAN COLLEGE OF PHYSICIANS - AMERICAN SOCIETY OF INTERNAL MEDICINE]

In 1997 the American College of Physicians (ACP) and the American Society of Internal Medicine (ASIM) merged to form the nation's largest medical specialty society with over 115,000 members. Since 1997, they were known as ACP-ASIM. In May 2004, the College changed its name back to simply ACP.

Over 95,000 of ACP members are general Internists (Internal Medicine), while about 20,000 physicians have a sub-specialty, including cardiology, nephrology, rheumatology, neurology, pulmonology, allergy and immunology, and gastroenterology. Thus, this organization is influential across much of the Forest product portfolio.

ACP is headquartered in Philadelphia and maintains an educational focus for members. Their Washington, D.C. office represents the strong policy arm of the organization and actively lobbies on health care issues. The D.C. office also houses the department responsible for creating office-based programs aimed at improving the practice of medicine.

Forest became a Corporate Sponsor of ACP in FY03, which provides additional marketing opportunities. ACP is actively participating in the Forest-led collaboration with APA to develop reasonable practice guidelines for managing chronic depression in the Primary Care Physician office-setting.

AMERICAN GERIATRIC SOCIETY

The American Geriatric Society (AGS) is the premier physician organization dedicated to improving the health and well being of all older adults. The majority of the 6,000 AGS members are Primary Care Physicians. In the last decade, AGS has become a pivotal force in shaping attitudes, policies and practices regarding health care for older people.

Most AGS members practice Internal Medicine, and may also be members of ACP.

AMERICAN MEDICAL DIRECTORS ASSOCIATION

While the majority of the American Medical Directors Association (AMDA) members are Medical Directors of Long Term Care Facilities and Nursing Homes, the organization has always served the interests of both medical directors and attending physicians. AMDA currently has over 8,700 members and a database of over 2,000 attending physicians, all of whom are Primary Care Physicians.

Forest has been a Corporate Sponsor of AMDA for the last few years. In 2002, AMDA revised their Depression Guidelines for Residents of LTC/NH, and expect to publish them by mid-2003. Forest Professional Relations is the major sponsor of this endeavor, providing financial, technical, and information support.

Forest helped co-sponsor AMDA's major project in drug safety in LTC/NH, Multidisciplinary Medication Management Tool Kit, focusing on reducing errors. Selection of drugs with low potential drug interactions and drugs that are well tolerated by an elderly population are the core themes. These Kits, which were introduced at AMDA's Annual Meeting in March 2003, may be purchased for distribution to LTC/NH as a high-value added program.

Forest has committed to provide major sponsorship of AMDA's Practice Guideline on the Management of Falls in LTC/NH. A body of evidence supports changing the current Guidelines: evaluating medication for potential drug interactions, changing drug therapies to reduce drug interactions and side effects, rather than discontinuing anti-depressants.

Forest has committed to provide major sponsorship of AMDA's Practice Guideline on Dementia, which is scheduled to begin revisions 4th quarter 2003. Publication is estimated as second-half 2004.

AMERICAN ACADEMY OF CHILD AND ADOLESCENT PSYCHIATRY

The American Academy of Child and Adolescent Psychiatry (AACAP) focus is treating children affected by mental, behavioral or developmental disorders, and improving the quality of life for their families. The majority of its 6,500 members are child and adolescent psychiatrists, who actively research, evaluate, diagnose, and treat psychiatric disorders.

During FY04 Forest Professional Relations will work with AACAP to explore the potential for consensus guidelines on treatment of pediatric depression. Results from any AACAP projects will be shared with APA, AAFP and the American Academy of Pediatrics.

NATIONAL ALLIANCE FOR THE MENTALLY ILL

The National Alliance for the Mentally Ill (NAMI) is a nonprofit, grassroots, self-help, support and advocacy organization of consumers, families, and friends of people with severe mental illnesses, such as schizophrenia, major depression, bipolar disorder, obsessive-compulsive disorder, and anxiety disorders. The "traditional" focus of NAMI has been on more severe mental illness, though they have recently begun involvement with more moderate disorders that are managed in a non-psychiatric setting.

Founded in 1979, NAMI has more than 210,000 members who seek equitable services for people with severe mental illnesses, which are known to be physical brain disorders. Working on the national, state, and local levels, NAMI provides education about severe brain disorders, supports increased funding for research, and advocates for adequate health insurance, housing, rehabilitation, and jobs for people with serious psychiatric illnesses.

NAMI has an active lobby effort, operating primarily at the State level with some action at the Federal level. Insurance parity and open formularies are two of their positions.

Forest has been a major Corporate Sponsor of NAMI since 2000.

NATIONAL MENTAL HEALTH ASSOCIATION

Established in 1909, the National Mental Health Association (NMHA) is the country's oldest and largest nonprofit organization addressing all aspects of mental health and mental illness. With more than 340 affiliates nationwide, NMHA works to improve the mental health of all Americans, especially the 54 million individuals with mental disorders, through advocacy, education, research and service.

NMHA's foundation is consumer-oriented education. In recent years, NMHA has become a strong lobby in support of insurance parity and open formularies. Their national/federal lobbying effort is as strong as their chapter-based State activity.

Forest has been a major Corporate Sponsor of NMHA since 2000, and participates in several of their educational conferences.

NMHA has a very effective grassroots organization, which devotes significant effort in lobbying State Health Departments on maintaining mental health care budgets, including supporting an open Medicaid drug formulary. Forest has expanded its involvement with NMHA, creating an information collaboration to assist mutual efforts at the State policy level.

DEPRESSION AND BIPOLAR SUPPORT ALLIANCE

[PREVIOUS NAME: NATIONAL DEPRESSIVE AND MANIC-DEPRESSIVE ASSOCIATION]

The mission of the Depression and BiPolar Support Alliance (DBSA) is to educate patients, families, professionals, and the public concerning the nature of depressive and manic-depressive illnesses as treatable medical diseases; to foster self-help for patients and families; to eliminate discrimination and stigma; to improve access to care; and to advocate for research toward the elimination of these illnesses.

The DBSA is the nation's largest patient-directed, illness-specific organization. Of the 3 largest patient advocacy groups, it is the only one that focuses on depression disorders. DBSA has a nationwide grassroots network of chapters and support groups. It is governed by a 15-member board of directors and guided by a 65-member Scientific Advisory Board composed of the leading researchers and clinicians in the field of mood disorders.

Forest has been a major Corporate Sponsor of DBSA since 2000.

ANXIETY DISORDERS ASSOCIATION OF AMERICA

The Anxiety Disorders Association of America (ADAA) is the only national, non-profit membership organization dedicated to informing the public, healthcare professionals and legislators that anxiety disorders are real, serious and treatable.

Members include clinicians and researchers who treat and study anxiety disorders, individuals with anxiety disorders and their families, and other interested individuals.

ADAA is a relatively small organization, which hopes to expand its influence in the next few years. ADAA is very open to active collaboration with industry, including participation in public relations activities. Forest has been a Corporate Sponsor since 2000.

Marketing opportunities with ADAA will increase when Lexapro labeling expands to include anxiety disorders. At that time, Forest can take advantage of opportunities to disseminate important brand information to their members.

Appendix VIII