THIRTY-FIFTH ANNUAL REPORT

of the

RESEARCH ADVISORY PANEL OF CALIFORNIA

2005

Prepared for the

LEGISLATURE AND GOVERNOR

RESEARCH ADVISORY PANEL OF CALIFORNIA

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2005 PANEL MEMBERS

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This report represents a consensus among Panel members acting as individual experts. It does not represent policies or positions of the appointing agencies nor have those agencies been consulted by the Panel during its function or during the preparation of this report.

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SUMMARY OF 2005 PANEL ACTIVITIES

During 2005 the Panel reviewed thirty-six new research study submissions. A total of thirty-three new research studies and one revision were approved by the Panel. Fourteen Independent studies were approved, of which nine were human studies and five were non-human studies. Eighteen Multicenter Clinical Drug Trial studies were approved. One Drug Abuse Treatment study was approved.

The Panel closed fifty-eight research studies during the year 2005. Twenty-one Independent studies were closed, of which eighteen were human studies and three were non-human studies. Thirty-four Multicenter Clinical Drug Trial studies were closed. Three Drug Abuse Treatment studies were closed..

At the end of 2005 the Panel was monitoring 140 research projects. Note Appendices A, B, and C for specific listings.

As part of the Panel's supervisory responsibility, ongoing projects are monitored by means of annual reports, AE reports and site visits; and approval may be withdrawn if activities deviate significantly from the approved protocol.

Table 1 is a list of the studies approved by the Panel in 2005 and Table 2 is a list of the studies closed by the Panel in 2005.

TABLE 1

RESEARCH STUDIES
APPROVED IN 2005

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Selena E. Barrett, Ph.D. Ernest Gallo Clinic & Research Center 5858 Horton Street, Suite 200 Emeryville, CA 94608	The role of cannabinoids and ibogaine in the treatment of alcoholism and drug addiction
Ronald W. Barrett, Ph.D. XenoPort, Inc. 3410 Central Expressway Santa Clara, CA 95051	Gamma Hydroxybutyrate as an Agonist at the GABA-B Receptor

Cephalon, Inc. Frazer, Pennsylvania	A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of ORAVESCENT Fentanyl Citrate for the Management of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Low Back Pain
Cephalon, Inc. Frazer, Pennsylvania	A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of ORAVESCENT Fentanyl Citrate in Opioid-Tolerant Patients With Cancer and Breakthrough Pain
Cephalon, Inc. Frazer, Pennsylvania	A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of ORAVESCENT Fentanyl Citrate for the Management of Breakthrough Pain in Opioid-Tolerant Patients With Chronic Neuropathic Pain
Cephalon, Inc. Frazer, Pennsylvania	A 4-Week, Open-Label Extension Study of ACTIQ (Oral Transmucosal Fentanyl Citrate [OTFC ®] Treatment for Opioid-Tolerant Children and Adolescents with Breakthrough Pain
Cephalon, Inc. Frazer, Pennsylvania	An Open-Label, 12-Month Study to Evaluate the Safety, Tolerability, and Efficacy of ORAVESCENT Fentanyl Citrate for the Management of Breakthrough Pain in Opioid-Tolerant Patients With Chronic Noncancer Pain
Cephalon, Inc. Frazer, Pennsylvania	Evaluation of Safety, Tolerability, and Pharmacokinetics of a 200 ug Single Dose of OraVescent Fentanyl Citrate Administered Buccally to Opioid-Tolerant Cancer Patients with or without Oral Mucositis

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Douglas Fry NORAC, Inc. 405 South Motor Avenue Azusa, CA 91702-3232	Preparation of Ibogaine and Its Analogs and Derivatives
Grunenthal GmbH Research and Development Aachen, Germany	Randomized, multicenter, double blind, parallel-group study assessing analgesic efficacy & safety of different dosages of GRT0151Y bid compared to active comparator bid & placebo bid in subjects with chronic knee-joint osteoarthritis
Halozyme Therapeutics, Inc. San Diego, CA 92121	Increased Flow Using Subcutaneously Enhanced Morphine (INFUSE-Morphine) Study: A Phase IIIB, double-blind, randomized, crossover study comparing the pharmacokinetics, safety and tolerability of morphine administered subcutaneously with and without human recombinant hyaluronidase (HYLENEX) and intravenously
Reese T. Jones, M.D. Dept of Psych & Langley Porter 401 Parnassus Avenue San Francisco, CA 94143-0984	Double-Blind, Placebo-Controlled, Assessment of Intravenous Methamphetamine and Modafinil Interactions
Ari Kalechstein, Ph.D. UCLA Neuropsychiatric Inst. 740 Westwood Plaza, Rm. A8-144 NPI Los Angeles, CA 90024	Methamphetamine Dependence: Treating Neurocognitive Impairment
Jon D. Levine, M.D., Ph.D. UCSF Box 0440 San Francisco, CA 94143-0440	Mechanisms of Pain Control: V. Analgesic Combinations for Post-Operative Pain–Kappa Opioids and Morphine

John E. Mendelson, M.D. California Pacific Med Center Castro & Duboce Sts., Room #151 San Francisco, CA 94114	Bioavailability and Urinary Excretion of Oral L-Methamphetamine
Robert O. Messing, M.D. Ernest Gallo Clinic & Research Center 5858 Horton Street, Suite 200 Emeryville, CA 94608	Protein kinase C epsilon (PKCe) in Responses to Cannabinoids
Thomas F. Newton, M.D. UCLA / ISAP Clinical Trials Ops 760 Westwood Plaza Box 12, NPI 175919 Los Angeles, CA 90024	Phase 1, Double-Blind, Placebo-Controlled Assessment of Potential Interactions between Intravenous Methamphetamine and GBR 12909
Thomas F. Newton, M.D. UCLA / ISAP Clinical Trials Ops 760 Westwood Plaza Box 12, NPI 175919 Los Angeles, CA 90024	Modafinil as a Treatment for Methamphetamine Dependence: Initial Safety, Subjective Effects, and Brain Functioning - Pilot study
Thomas F. Newton, M.D. UCLA / ISAP Clinical Trials Ops 760 Westwood Plaza Box 12, NPI 175919 Los Angeles, CA 90024	The Effects of Modafinil on Tests of Inhibitory Control in Methamphetamine Addiction
Thomas F. Newton, M.D. UCLA / ISAP Clinical Trials Ops 760 Westwood Plaza Box 12, NPI 175919 Los Angeles, CA 90024	Laboratory Models of Cocaine Self Administration

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Pain Therapeutics, Inc. South San Francisco, California	A Multicenter, Randomized, Double-Blind, Active- and Placebo-Controlled, Phase III, Efficacy and Safety Study of Oxycodone and Low-Dose Naltrexone (PTI-801) in Patients with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Hip or Knee
Pain Therapeutics, Inc. South San Francisco, California	A Long-Term, Open-Label, Safety Study of Oxycodone HC1 and Low-Dose Naltrexone HC1 (PTI-801) in Patients with Moderate to Severe Chronic Low Back Pain or with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Hip or Knee
Mark Perrone, Ph.D. Genomics Inst Novartis Rsrch Fdn 10675 John Jay Hopkins Drive San Diego, CA 94608	Application for Non-Human Research Using Schedule I Controlled Substance - Effects of Novel Agents on Food Intake, Weight Gain and Weight Loss in Rodents, Determination of Stimulation and Blockade of CB1 Receptor
Matthew A. Schreiber, M.D., Ph.D. Ernest Gallo Clinic & Research Ctr 5858 Horton Street Ste 200 Emeryville, CA 94608	Pharmacological and genetic study of the effects of 3,4- methylenedioxymethamphetamine (MDMA) using a model organism, the nematode Caenorhabditis elegans
Shire Pharmaceutical Dvlpmt., Inc. Rockville, Maryland	A Phase III, Multi-Center, Open-label Study of Methylphenidate Transdermal System® (MTS) in Pediatric Patients aged 6-12 with Attention-Deficit/Hyperactivity Disorder (ADHD)

Shire Pharmaceutical Dvlpmt., Inc. Rockville, Maryland	A Phase IIIB, Rndmzd, Dbl-Blind, Multi-Ctr, Placebo-Cntrld, Dose-Optzmd, 3-way X-Over Study to Assess the Efficacy, Effect, Tolerability and Safety of 4 & 6 hour Wear Times of Methylphenidate Transderm Sys (MTS) in Pedi Sbjcts aged 6-12 w/ ADHD
Shire Pharmaceutical Dvlpmt., Inc. Rockville, Maryland	A Phase III, Randomized, Double-blind, Multi-center, Placebo-controlled, Parallel-group, Forced Dose Titration, Safety and Efficacy Study of SPD465 in Adults with Attention-Deficit Hyperactivity Disorder (ADHD)
Shire Pharmaceutical Dvlpmt., Inc. Rockville, Maryland	A Prospective, Open-Label, Multi-Center Study Evaluating the Safety and Tolerability of Methylphenidate Transdermal System (MTS) in Children Aged 6 - 12 Previously Treated with Extended Release Methylphenidate Product
Shire Pharmaceutical Dvlpmt., Inc. Rockville, Maryland	A Phase II, Randomized, Double-blind, Multi-center, Placebo-controlled, Crossover Study of SPD464 in Adults with Attention-Deficit Hyperactivity Disorder (ADHD)
Steven Shoptaw, Ph.D. Semel Inst of Neurosci & Hum Behav. 11075 Santa Monica Blvd. #200 Los Angeles, CA 90025	A Randomized, Double-Blind, Placebo-Controlled Evaluation of Bupropion vs Placebo for the Treatment of Methamphetamine Dependence
Solvay Pharmaceuticals, Inc.	Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Efficacy, Safety, and Tolerability Study of Dronabinol MDI in the Acute Treatment of Migraine Headache
ZARS, Inc. Salt Lake City, Utah	An Open-Label, Long-Term Safety Study to Evaluate the Safety of the ZR02-01 Matrix Transdermal Fentanyl Patch for the Treatment of Osteoarthritis Pain

Table 1 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
ZARS, Inc. Salt Lake City, Utah	An Open-Label Safety Study to Evaluate the Safety of the ZR-02-01 Matrix Transdermal Fentanyl Patch for the Treatment of Moderate to Severe, Non-malignant Chronic Pain

TABLE 2

RESEARCH STUDIES CLOSED OR
DISCONTINUED IN 2005

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Donald I. Abrams, M.D. UCSF Community Consortium 3180 18th Street, Suite 201 San Francisco, CA 94110-2042	Marijuana in Combination with Opioid for Cancer Pain: Pilot Study.
ALZA Corporation Mountain View, California	ALZA Protocol M03-644
ALZA Corporation Mountain View, California	ALZA Protocol C-2003-008
ALZA Corporation Mountain View, California	ALZA Protocol C-2003-017
ALZA Corporation Mountain View, California	ALZA Protocol C-2004-016
Jed Black, M.D. Stanford Sleep Disorders Clinic 401 Quarry Road, Suite 3301 Stanford, CA 94305	Open Label, Multi-Center, Safety Trial Studying the Effects of Orally Administered Xyrem® (Sodium Oxybate)
Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, Conneticut	A Phase I dbl-blind, dbl-dummy, rndmzd 3 period cross-over study designed to assess the abuse potential of 2 doses of NS 2330 relative to placebo and 10mg methamphetamine in recreational stimulant users who demonstrate a response to methamphetamine

Cephalon, Inc. Frazer, Pennsylvania	A Multicenter, Double-Blind, Placebo-Controlled Study of OraVescent®Fentanyl Citrate for the Treatment of Breakthrough Pain in Opioid-Tolerant Cancer Patients
Cephalon, Inc. Frazer, Pennsylvania	Evaluation of Safety, Tolerability, and Pharmacokinetics of a 200 ug Single Dose of OraVescent Fentanyl Citrate Administered Buccally to Opioid-Tolerant Cancer Patients with or without Oral Mucositis
Peggy A. Compton, RN, Ph.D. UCLA School of Nursing Box 956918 Los Angeles, CA 90095-6918	Hyperalgesia in Methadone Maintained Patients: Can it be Treated with Oxycodone?
Drug Abuse Sciences, Inc. Germantown, Tennessee	A 6-month open-label, prospective, multicenter safety study of Naltrexone Depot as relapse prevention therapy of heroin-dependent subjects following detoxification with Suboxone®
Suzanne L. Dibble, DNSc, R.N. UCSF School of Nursing Box 0646, laurel Heights, Rm 340 San Francisco, CA 94143-0646	Treating Chemotherapy-Induced Delayed Nausea with Cannabinoids
Joel E. Dimsdale, M.D. University of California, San Diego 9500 Gillman Drive La Jolla, CA 92093-0804	Effects of Common Opioid Medications on Sleep Architecture and Next-Day Fatigue
Elan Pharmaceuticals, Inc. San Diego, CA 92121	An Open-label, Multicenter Study of the Safety and Efficacy of Combined Intrathecal Infumorph® and Ziconotide (Prialt™): Addition of Infumorph® in Patients Receiving Prialt™ for Severe Chronic Pain

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Elan Pharmaceuticals, Inc. San Diego, CA 92121	An Open-label, Multicenter Study of the Safety and Efficacy of Combined Intrathecal Infumorph® and Ziconotide (Prialt™): Addition of Prialt™ in Patients Receiving Infumorph® for Severe Chronic Pain
Endo Pharmaceuticals Inc. Chadds Ford, Pennsylvania	A Double-Blind, Randomized, Sham Procedure Controlled Study to Evaluate the Efficacy and Safety of a Single Epidural Dose of SKY0401 in the Management of Post-Operative Pain in Patients Undergoing Hip Arthroplasty with Regional Anesthesia
Endo Pharmaceuticals Inc. Chadds Ford, Pennsylvania	A Double-Blind, Randomized, Sham Procedure Controlled Study to Evaluate the Efficacy and Safety of a Single Epidural Dose of SKY0401 in the Management of Post-Operative Pain in Patients Undergoing Hip Arthroplasty with Regional Anesthesia
Endo Pharmaceuticals Inc. Chadds Ford, Pennsylvania	A Single-Dose Evaluation of the Safety and Efficacy of Oxycodone/Acetaminophen for Acute Postoperative Pain in Pediatric Patients
Endo Pharmaceuticals Inc. Chadds Ford, Pennsylvania	An Open-Label, Long-Term Effectiveness and Safety Study of Oxymorphone Extended Release Tablets in Patients with Cancer or Neuropathic Pain
Milton K. Erman, M.D. Pacific Sleep Medicine Svcs Inc. 9834 Genesee Avenue, Suite 328 La Jolla, CA 92037	Open Label, Multi-Center, Safety Trial Studying the Effects of Orally Administered Xyrem® (Sodium Oxybate)

Ricahrd C. Graul, Pharm.D. 682 29th Ave San Francisco, CA 94121	Mechanisms of 3,4-methylenedioxymethamphetamine Toxicities
Dennis M. Israelski, M.D. San Mateo Medical Center 222 West 39th Avenue San Mateo, CA 94403	A Pilot Study of the Feasibility and Safety of Controlled Trials of Medical Marijuana to Relieve HIV-Associated Distal Symmetric Polyneuropathy; Other HIV-associated Pain; and HIV-associated Nausea, Anorexia, and Wasting
Dennis M. Israelski, M.D. San Mateo Medical Center 222 West 39th Avenue San Mateo, CA 94403	MMJ for HIV-associated DSPN: Adherence & Compliance Sub-Study
Johnson & Johnson Pharm Rsrch & Dvl Titusville, New Jersey	A 4-Week Multicenter, Phase IIB Study Comparing Efficacy and Safety of Ascending Doses of CG5503 PR Up To 233 mg BID and Oxycodone PR up to 20mg BID to Placebo in Subjects with Moderate to Severre Chronic Pain Due to Osteoarthritis of the Knee
Lorrin M. Koran, M.D. Stanford Univ. School of Medicine 401 Quarry Road Rm. 2363 Stanford, CA 94305-5721	Oral Morphine in Treatment Resistant Obsessive-Compulsive Disorder (OCD)
Ronald Kuczenski, Ph.D. UCSD School of Medicine 9500 Gillman Drive La Jolla, CA 92093-0603	Effects of GW Extracts on Methamphetamine-Induced Neurotoxicity
Jelveh Lameh, Ph.D. Molecular Research Institute 2495 Old Middlefield Way Mountain View, CA 94043	Pharmacochemical Studies of Opiate Narcotics

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
James T. McCracken, M.D. UCLA Neuropsychiatric Institute 300 UCLA Medical Plaza, Suite 1534A Los Angeles, CA 90095-6967	Methylphenidate in the Treatment of Hyperactivity and Impulsiveness in Children and Adolescents with Pervasive Developmental Disorder
Thomas F. Newton, M.D. UCLA Neuropsychiatric Inst. 740 Westwood Plaza, Rm. A7-372 NPI Los Angeles, CA 90024	Phase 1, Double-Blind, Placebo-Controlled Assessment of Potential Interactions between Intravenous Methamphetamine and GBR 12909
National Institute on Drug Abuse Bethesda, Maryland	Double-Blind, Placebo-Controlled, Dose Response Trial of Ondansetron for the Treatment of Methamphetamine Dependence
National Institute on Drug Abuse Bethesda, Maryland	Phase 2, Double-Blind, Placebo-Controlled Trial of Selegiline for Methamphetamine Relapse Prevention
Noven Pharmaceuticals Inc. Miami, Florida	Open Label Study of MethyPatch in Children with ADHD / Extension Continuation
Orphan Medical Minnetonka, Minnesota	Open Label, Multi-Center, Safety Trial Studying the Effects of Orally Administered Xyrem® (Sodium Oxybate)
Ortho-McNeil Pharmaceuticals Inc. Raritan, New Jersey	Comparison of the Safety and Efficacy of Patient Controlled Analgesia delivered by Fentanyl HCl Transdermal System versus Morphine IV Pump for Pain Management after Primary Unilateral Total Hip Replacement

Ortho-McNeil Pharmaceuticals Inc. Raritan, New Jersey	Comparison of the Safety and Efficacy of Patient Controlled Analgesia delivered by Fentanyl HCl Transdermal System versus Morphine IV Pump for Pain Management after Non-emergent Lower Abdominal and Pelvic Surgery
Pain Therapeutics, Inc. South San Francisco, California	A Multicenter, Randomized Placebo-Controlled, Phase III, Efficacy and Safety Study of PTI-821 in Patients with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Hip or Knee
Helen J. Parish, Director Pharmaceutical Sciences laboratory SRI International 333 Ravenswood Ave., PS 143 Menlo Park, CA 94025	Pulsatile Release/Controlled Release Dosage Form Development of Xyrem
Karin L. Petersen, M.D. UCSF Clinical Pain Research Center 1701 Divisadero Street, Suite 480 San Francisco, CA 94115	Randomized, Double-blind, Pilot Study to Compare the Analgesic Efficacy of Morphidex versus Morphine, Dextromethorphan, and Placebo Using the Heat/Capsaicin Sensitization Model
Progenics Pharmaceuticals Tarrytown, New York	A Double-Blind Placebo Controlled Study of Methylnaltrexone (MNTX) for the Relief of Symptomatic Constipation Due to Chronic Opioid Therapy in Patients with Advanced Medical Illness
Purdue Pharma L.P. Stamford, Connecticut	A Randomized, Multiple-dose, Double-blind, Placebo-controlled, Parallel-group Study Comparing the Safety and Efficacy of Hydromorphone HCl Extended-release and Duragesic® in Subjects with Non-malignant Pain

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
John M. Roll, Ph.D. Friends Research Inst., Inc. 11075 Santa Monica Blvd., Suite 350 Los Angeles, CA 90025	Human Behavioral Pharmacology of GHB
John M. Roll, Ph.D. Friends Research Inst., Inc. 11075 Santa Monica Blvd., Suite 350 Los Angeles, CA 90025	Human Methamphetamine Use: A Modell
Murray H. Rosenthal, D.O. HealthQuest Clinical Trials 3625 Ruffin Road, Suite 100 San Diego, CA 92123	A Polysomnographic Study Measuring the Effect of Avinza on Sleep in Osteoarthritis Patients with Complaints of Sleep Disturbances Attributed to Moderate to Severe Chronic Pain
Michael C. Rowbotham, M.D. UCSF Pain Clinical Research Center 1701 Divisadero St., Suite 480 San Francisco, CA 94115	The effect of intravenous remifentanil on the experimental heat/ capsaicin sensitization model in chronic pain patients
Sention, Inc. Providence, Rhode Island	A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Assess the Safety, Tolerability, and Efficacy of Titration and Treatment with C105 in Subjects with Mild Cognitive Impairment (MCI)
Shire Pharmaceutical Development Rockville, Maryland	A Phase III, Multi-center, 18-month, Open-label Safety, Tolerability and Efficacy Study of Adderall XR® in the Treatment of Adolescents Aged 13-18 with Attention Deficit Hyperactivity Disorder (ADHD)

Shire Pharmaceutical Development Rockville, Maryland	A Phase IIIb, Open-Label, Multi-Ctr Study to Assess Safety, Tolerability, and Effectiveness Associated with the use of ADDERALL XR® in Adults with Attention Deficit Hyperactivity Disorder and Evaluate an ADHD-specific Novel Quality of Life Measure
Shire Pharmaceutical Development Rockville, Maryland	A Phase III, Randomized, Multi-Center, Double-Blind, Parallel-Group, Placebo-Controlled Safety and Efficacy Study of ADDERALL XR® with an Open-label Extension, in Adolescents Aged 13-17 with Attention Deficit Hyperactivity Disorder (ADHD)
Shire Pharmaceutical Development Rockville, Maryland	A Phase 2, Randomized, Double-blind, Multi-center, Placebo- and Active-controlled, Crossover Study of SPD465 in Adults with Attention-Deficit Hyperactivity Disorder (ADHD)
Shire Pharmaceutical Development Rockville, Maryland	A Randomized, Double-Blind, Parallel-Group, Analog Classroom Study, Evaluating Adderall XR® vs. Strattera™, Dosed once-daily, in Children aged 6-12 with Attention Deficit Hyperactivity Disorder (ADHD)
Shire Pharmaceutical Development Rockville, Maryland	A Phase II, Randomized, Double-blind, Multi-center, Placebo- and Active-controlled, Crossover Study of SPD465 in Adolescents with Attention-Deficit Hyperactivity Disorder (ADHD)
Shire Pharmaceutical Development Rockville, Maryland	A 24-Month, Open-Label Study of Adderall XR® in Adults with Attention Deficit Hyperactivity Disorder

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Shire Pharmaceutical Development Rockville, Maryland	A Phase II, Rndmzd, Dbl-Blind, Multi-Center, Placebo-Cntrld, Crossover Study, Designed to Assess the Time Course of Treatment Effect, Tolerability and Safety of Methylphenidate Transdermal System® (MTS) in Pediatric Patients aged 6-12 with ADHD
Shire Pharmaceutical Development Rockville, Maryland	A Phase III, Rndmzd, Dbl-Blind, Multi-Center, Parallel Grp, Placebo-Cntrld, Dose Optimization Study, Designed to Evalutate the Safety & Efficacy of Methylphenidate Transdermal System® (MTS) vs. CONCERTA® in Pediatric Patients aged 6-12 with ADHD
Shire Pharmaceutical Development Rockville, Maryland	A Phase III, Randomized, Double-blind, Multi-center, Placebo-controlled, Parallel-Group, Safety and Efficacy Study of SPD465 with an Open-label Extension in Adolescents with Attention-Deficit Hyperactivity Disorder (ADHD)
SkyePharma, Inc. San Diego, California	SkyePharma Protocol SKY0401-020
Mark S. Wallace, M.D. UCSD Clinical Pain Research 9500 Gilman Drive # 0924 La Jolla, CA 92093-0924	Analgesic Efficacy of Smoked Cannabis in Refractory Cancer Pain

ZARS, Inc. Salt Lake City, Utah	Double-Blind, Parallel, Randomized, Placebo-Controlled, 12-Week Efficacy and Safety Assessment of ZR-02-01 in the Treatment of Chronic, Moderate to Severe Osteoarthritis (OA) Pain

APPENDIX A

CURRENTLY APPROVED *(December 31, 2005)*
INDEPENDENT SCHEDULE I AND SCHEDULE II
CONTROLLED SUBSTANCE
RESEARCH STUDIES

Principal Investigator	Title of Study
Donald I. Abrams, M.D. UCSF Community Consortium 3180 18th Street, Suite 201 San Francisco, CA 94110-2042	The Effects of Marijuana on Neuropathic Pain in HIV-Related Peripheral Neuropathy: A Randomized, Double-Blind, Placebo-Controlled Study
Donald I. Abrams, M.D. UCSF Community Consortium 3180 18th Street, Suite 201 San Francisco, CA 94110-2042	The Effect of Marijuana on Neuropathic Pain in HIV-Related Peripheral Neuropathy
Mark A. Agius, M.D. Dept. of Neurology University of California, Davis 1515 Newton Court Room 510 Davis, CA 95616	Cannabis for Spasticity/Tremor in MS: Placebo Controlled Study
James T. Arnold, Ph.D. Systems and Techniques Lab. Varian Associates 3075 Hansen Way Palo Alto, CA 94304-1025	Chemical Vapor Analysis of Marijuana and Other Drugs of Abuse
Mark G. Barad, M.D., Ph.D. UCLA Dept Psych & Biobehav Sci 695 Charles E. Young Drive South Los Angeles, CA 90095-1761	Cannabinoids in Fear Extinction
Selena E. Barrett, Ph.D. Ernest Gallo Clinic & Research Ctr 5858 Horton Street, Suite 200 Emeryville, CA 94608	The role of cannabinoids and ibogaine in the treatment of alcoholism and drug addiction

Appendix A Cont.

Principal Investigator	Title of Study
Ronald W. Barrett, Ph.D. XenoPort, Inc. 3410 Central Expressway Santa Clara, CA 95051	Gamma Hydroxybutyrate as an Agonist at the GABA-B Receptor
Phillip E. Bickler, M.D., Ph.D. UCSF Dept. of Anes. & Periop. Care 513 Parnassus Ave. San Francisco, CA 94143-0542	Inhaled carbon dioxide and apnea during intravenous sedation
Nancy E. Buckley, Ph.D. California State Polytechnic Univ. 3801 W. Temple Ave. Pomona, CA 91768	The Role of the Peripheral Cannabinoid (CB2) Receptor Activation in Immune Function
Jeremy S. Caldwell, Ph.D. Genomics Inst Novartis Research Fdn 10675 John Jay Hopkins Drive San Diego, CA 92121	High-Throughput Screening of Known Drugs for Novel Biological Activity in Cell-based Assays
Karen Chang, Ph.D. ALZA Corp. 1900 Charleston Road Mountain View, CA 94039-7210	Purity Determination, Morphine and Hydromorphone
Lin Chang, M.D. W. Los Angeles VA Medical Center 11301 Wilshire, Bldg 115, Rm 223 Los Angeles, CA 90073	Neuroendocrine Alterations in Fibromyalgia and IBS
Arthur K. Cho, Ph.D. Dept./Pharmacology, 23-272 CHS UCLA School of Medicine 10833 Le Conte Avenue Los Angeles, CA 90024-1721	Studies on Distribution and Metabolism of Narcotics in Animals

Principal Investigator	Title of Study
Kent S. Chu, Ph.D. YJ Bio-Products 11353 Pyrites Way, Suite 14 Cordova, CA 95670	Immunochromatographic Test Device for THC and LSD
Laura Colin Biostride, Inc. 1201 Douglas Avenue Redwood City, CA 94063	Research of Novel Technologies for Development of Antibodies and Immunoassay Techniques to Drugs of Abuse and Controlled Compounds of Interest
Jody Corey-Bloom, M.D. UCSD Clinical Research Ctr. 9500 Gilman Drive La Jolla, CA 92093-0620	Short-Term Effects of Cannabis Therapy on Spasticity in MS
Sean Drummond, Ph.D. UCSD/San Diego VAMC 3350 La Jolla Village Drive La Jolla, CA 92161	Sleep and Medicinal Cannabis
Ronald J. Ellis, M.D. UCSD HIV Neurobehav. Rsch. Ctr. 150 W. Washington St., 2nd Floor San Diego, CA 92103	Placebo-controlled, Double-blind Trial of Medicinal Cannabis in Painful HIV-Neuropathy
Laura J. Esserman, M.D. UCSF Breast Care Center 1600 Divisadero St. Box 1710 San Francisco, CA 94143	Postoperative Pain Control with Fentanyl Patch in Patients undergoing Mastectomy and Tram Flap Reconstruction
Aaron Ettenberg, Ph.D. Dept. Psychology, UC Santa Barbara Santa Barbara, CA 93106-9660	Dopamine Involvement in Opiate and Stimulant Drug Reinforcement

Appendix A Cont.

Principal Investigator	Title of Study
Frederick D. Frankel, Ph.D. UCLA Department of Psychiatry 300 UCLA Medical Plaza Los Angeles, CA 90095-6769	Social Skills Training for Medicated Children
Douglas Fry The NORAC Co., Inc. 405 S Motor Ave., POB 577 Azusa, CA 91702-0706	Research on the Synthesis of Schedule I Controlled Substances: delta-9-THC and LAAM
Douglas Fry The NORAC Co., Inc. 405 S Motor Ave., POB 577 Azusa, CA 91702-0706	"Preparation of Ibogaine and Its Analogs and Derivatives"
Alan Gevins SAM Technology, Inc. 425 Bush Street 5th Floor San Francisco, CA 94108.	Neurocognitive Index of Cannabis Effects System
Mark A. Geyer, Ph.D. Dept. of Psychiatry - 0804 University of Calif, San Diego 9500 Gilman Drive La Jolla, CA 92093-0804	Behavioral and Cytoflourimetric Studies of Psychoactive Drugs in Rats
Terry E. Grimmer, M.S. Berlex Biosciences 2600 Hilltop Drive Richmond, CA 94804-0099	Synthesis of Pharmaceutical Research Compounds
Charles S. Grob, M.D. Harbor UCLA Medical Center 1000 West Carson Street Torrance, CA 90509	Effects of Psilocybin in Terminal Cancer Patients with Anxiety

Principal Investigator	Title of Study
Kanthi F. Hettiarachchi, Ph.D. SRI International 333 Ravenswood Avenue Menlo Park, CA 94025	Analysis of Cannabinoids
Richard A. Houghten, Ph.D. Torrey Pines Inst./Molecular Study 3550 General Atomics Ct. San Diego, CA 92121	Biochemical Basis for the CNS Actions of Methaqualone
Michael Irwin, M.D. UCLA Neuropsychiatric Institute 300 UCLA Medical Plaza Ste 3109 Los Angeles, CA 90095-7076	Cocaine Dependence: Sleep and Cytokines
J. David Jentsch, Ph.D. UCLA Department of Psychology 405 Hilgard Ave; B630 Franz Hall Los Angeles, CA 90095-1563	Neurocognitive and Chemical Effects of Entactogenic and Cannabinoidergic Drugs
S.V. Penelope Jones, Ph.D. UCSD School of Medicine 9500 Gilman Drive La Jolla, CA 92093-0603	Effects of GHB on the Mesolimbic Dopaminergic System
Ari Kalechstein, Ph.D. UCLA Neuropsychiatric Inst. 740 Westwood Plaza, Rm. A8-144 NPI Los Angeles, CA 90024	Methamphetamine Dependence: Treating Neurocognitive Impairment"
Thomas B. King Alexza Molecular Delivery Corp. 1001 East Meadow Circle Palo Alto, CA 94303	Development of an FDA Approved Dronabinol Pharmaceutical Product for Inhalation Delivery

Appendix A Cont.

Principal Investigator	Title of Study
George F. Koob, Ph.D. Dept of Neuropharmacol. CVN-7 The Scripps Research Institute 10666 N Torrey Pines Rd. La Jolla, CA 92037	Central Mechanisms of Opiate Reinforcement and Dependence
George F. Koob, Ph.D. Dept of Neuropharmacol. CVN-7 The Scripps Research Institute 10666 N Torrey Pines Rd. La Jolla, CA 92037	Neuronal Substrates of Cocaine Reward
Helen Lavretsky, M.D. UCLA Neuropsychiatric Institute 760 Westwood Plaza Rm 37-425 Los Angeles, CA 90024	Intervention Clinical Trial for Geriatric Depression: A Double-blind Placebo-Controlled Trial of Methylphenidate (Ritalin) Augmentation of Citalopram (Celexa) in Depressed Patients at Least 70 Years of Age
Nancy M. Lee, Ph.D. Forbes Norris ALS/MDA Rsrch Ctr. 2351 Clay Street Suite 416 San Francisco, CA 94115	Role of Cannabinoid Receptors in Central Nervous System Functions and Diseases
Jon D. Levine, M.D., Ph.D. UCSF Dept. Oral&Maxillofac Surgery San Francisco, CA 94143-0440	Mechanisms of Pain Control: V. Analgesic Combinations for Post-Operative Pain–Kappa Opioids and Morphine.
Marie Lin, Ph.D. R.Ph. Lin-Zhi International, Inc. 687 North Pastoria Ave Sunnyvale, CA 94085	Lin-Zhi Immunoassay Development Study
Thomas D. Marcotte, Ph.D. UCSD HIV Neurobehav. Rsch. Ctr. 150 W. Washington St., 2nd Floor San Diego, CA 92103	Impact of Repeated Cannabis Treatments on Driving Abilities

Principal Investigator	Title of Study
James J. McGough. M.D. UCLA Child Treatment Rsch Grp 300 UCLA Medical Plaza # 1534A Los Angeles, CA 90095-6967	Response Variability in Stimulant Treatment of ADHD
John E. Mendelson, M.D. Psychiatry and Langley Porter, UCSF 401 Parnassus Ave., Box CPR-0984 San Francisco, CA 94143-0984	Pharmacokinetics of Intranasal and Smoked Methamphetamine
John E. Mendelson, M.D. Psychiatry and Langley Porter, UCSF 401 Parnassus Ave., Box CPR-0984 San Francisco, CA 94143-0984	Pharmacokinetic Interactions between the Selegiline Transdermal Delivery System and d-Methamphetamine
John E. Mendelson, M.D. Psychiatry and Langley Porter, UCSF 401 Parnassus Ave., Box CPR-0984 San Francisco, CA 94143-0984	Effects of Cocaine Agonist Therapy on Cocaine Self-Administration, Tolerance, and Craving
John E. Mendelson, M.D. Psychiatry and Langley Porter, UCSF 401 Parnassus Ave., Box CPR-0984 San Francisco, CA 94143-0984	Clinical Pharmacology of l-Methamphetamine
John E. Mendelson, M.D. Psychiatry and Langley Porter, UCSF 401 Parnassus Ave., Box CPR-0984 San Francisco, CA 94143-0984	Interaction Between Oral Reserpine and Intravenous Methamphetamine
John E. Mendelson, M.D. Psychiatry and Langley Porter, UCSF 401 Parnassus Ave., Box CPR-0984 San Francisco, CA 94143-0984	Interaction Between the Serotonin Reuptake Blocker Paroxetine and Methamphetamine

Appendix A Cont.

Principal Investigator	Title of Study
Karen Miotto, M.D. UCLA Neuropsychiatric Inst. 760 Westwood Plaza Room 37-384C Los Angeles, CA 90095	GHB: Effects, Withdrawal and Treatmen"
Karel Z. Newman, Ph.D. Biosite Incorporated 9975 Summers Ridge Road San Diego, CA 92121	Development of In-vitro Immunoassays for the Detection of Abused Substances
Thomas F. Newton, M.D. UCLA / ISAP Clinical Trials Ops 760 Westwood Plaza, Box 12, NPI Los Angeles, CA 90024	Perindopril - Methamphetamine Interaction Study
Thomas F. Newton, M.D. UCLA / ISAP Clinical Trials Ops 760 Westwood Plaza, Box 12, NPI Los Angeles, CA 90024	Modafinil as a Treatment for Methamphetamine Dependence: Initial Safety, Subjective Effects, and Brain Functioning - Pilot study
Thomas F. Newton, M.D. UCLA / ISAP Clinical Trials Ops 760 Westwood Plaza, Box 12, NPI Los Angeles, CA 90024	Double-Blind, Placebo-Controlled Assessment of Potential Interactions between Intravenous Methamphetamine and Oral Bupropion
Thomas F. Newton, M.D. UCLA / ISAP Clinical Trials Ops 760 Westwood Plaza, Box 12, NPI Los Angeles, CA 90024	Laboratory Models of Cocaine Self Administration
Karno Ng, Ph.D. California State University San Marcos San Marcos, CA 92096-0001	New Qualitative and Quantitative Methods for the Detection of Gamma-hydroxybutyrate (GHB)

Principal Investigator	Title of Study
Stanley M. Parsons, Ph.D. Dept Chem & Biochem, UCSB Santa Barbara, CA 93106-9510	Rapid Detection of 4-hydroxybutyrate
Mark Perrone, Ph.D. 10675 John Jay Hopkins Drive San Diego, CA 92121	Application for Non-Human Research Using Schedule I Controlled Substance - Effects of Novel Agents on Food Intake, Weight Gain and Weight Loss in Rodents, Determination of Stimulation and Blockade of CB1 Receptor
John M. Polich, Ph.D. Dept. of Neuropharmacology The Scripps Research Institute 10550 North Torrey Pines Rd TPC10 La Jolla, CA 92037	Marijuana CNS Effects in Low- and High-Risk Adults
Robert Ramage Microgenics Corporation 46360 Fremont Boulevard Fremont, CA 94538	Use of Schedule I Controlled Substances for Cross Reactant Studies and Investigation of Customer Inquiries
Dorit Ron, Ph.D. Ernest Gallo Clinic & Research Ctr 5858 Horton Street Suite 200 Emeryville, CA 94608	Signaling Pathways Involved in the Mechanism of Action of the Anti-Addictive Drug Ibogaine
Michael C. Rowbotham, M.D. UCSF Pain Clinical Res. Cntr. 2233 Post St. Suite 104 San Francisco, CA 94115	The effect of intravenous remifentanil on the experimental heat/capsaicin sensitization model in chronic pain patients
Michael C. Rowbotham, M.D. UCSF Pain Clinical Res. Cntr. 2233 Post St. Suite 104 San Francisco, CA 94115	Evolution of Analgesic Tolerance During Long Term Treatment of Chronic Pain with Opioids

Appendix A Cont.

Principal Investigator	Title of Study
Matthew A. Schreiber, M.D., Ph.D. Ernest Gallo Clinic & Research Ctr 5858 Horton Street Ste 200 Emeryville, CA 94608	Pharmacological and genetic study of the effects of 3,4- methylenedioxymethamphetamine (MDMA) using a model organism, the nematode Caenorhabditis elegans
Rachel D. Schrier, Ph.D. UCSD Medical Center 200 W Arbor Drive MC 8416 San Diego, CA 92103-8416	Effects of Medicinal Cannabis on CD4 Immunity in Aids
Steven Shoptaw, Ph.D. Semel Inst of Neurosci & Hum Behav 11075 Santa Monica Blvd. #200 Los Angeles, CA 90025	A Randomized, Double-Blind, Placebo-Controlled Evaluation of Bupropion vs Placebo for the Treatment of Methamphetamine Dependence
Donald P. Tashkin, M.D. D Geffen School of Med at UCLA 10833 Le Conte Ave 37-131 CHS Los Angeles, CA 90095-1690	Cocaine Smoking Effects on Lung Immunity and Host Defense
Lawrence Toll, Ph.D. Neuroscience Department SRI International 333 Ravenswood Avenue Menlo Park, CA 94025	Biochemical Studies into Opiate Efficacies
Lawrence Toll, Ph.D. Receptor Pharmacology SRI International 333 Ravenswood Avenue Menlo Park, CA 94025	Receptor binding assays of blind and coded schedule I controlled substances pursuant to contracts with the National Institute on Drug Abuse
Edward Tung, Ph.D. Acon Laboratories 4108 Sorrento Valley Blvd. San Diego, CA 92121	Development of urine and/or oral-fluid based in-vitro diagnostic tests to detect the presence of the controlled substances MDMA, GHB and THC

Principal Investigator	Title of Study
Edward Tung, Ph.D. AZURE Institute 4108 Sorrento Valley Blvd. San Diego, CA 92121	Development of urine and/or oral-fluid based in-vitro diagnostic tests in the form of lateral flow rapid test format to detect controlled substances commonly abused and misused by individuals
David L. Valentine, Ph.D. Department of Earth Science U.C. Santa Barbara Santa Barbara, CA 93116	Isolation of bacteria capable of growth on gamma-hydroxybutyric acid (GHB) and its analogs
Jennifer L. Whistler, Ph.D. Ernest Gallo Clinic & Research Ctr 5858 Horton Street Suite 200 Emeryville, CA 94608	Endocytosis and Cannabinoid Receptors
Jennifer L. Whistler, Ph.D. Ernest Gallo Clinic & Research Ctr 5858 Horton Street Suite 200 Emeryville, CA 94608	Endocytosis and Opioid Receptors
Sharon B. Wigal, Ph.D. UCI Child Development Center 19722 MacArthur Blvd. Irvine, CA 92612	Pharmacokinetic and Pharmacodynamic Evaluation of Stimulant Drugs
Barth L. Wilsey, M.D. UC Davis Medical Center 4860 Y Street Suite 2700 Sacramento, CA 95817	A Double Blind, Active Placebo Controlled Crossover Trial of the Antinociceptive Effect of Smoked Marijuana on Subjects with Neuropathic Pain; Correlation with Changes in Mood, Cognition, and Psychomotor Performance
Justin A. Zivin, M.D., Ph.D. Dept. of Neurosciences, 0624 UCSD School of Medicine 9500 Gilman Drive La Jolla, CA 92093-0624	Therapy of Central Nervous System Ischemia

APPENDIX B

CURRENTLY APPROVED *(December 31, 2005)*
SCHEDULE II MULTICENTER
CLINICAL DRUG TRIAL STUDIES

Sponsor	Description or Title of Clinical Drug Trial Protocol
Cephalon, Inc. Frazer, Pennsylvania	A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of ORAVESCENT Fentanyl Citrate for the Management of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Low Back Pain
Cephalon, Inc. Frazer, Pennysylvania	A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of ORAVESCENT Fentanyl Citrate in Opioid-Tolerant Patients With Cancer and Breakthrough Pain
Cephalon, Inc. Frazer, Pennysylvania	A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of ORAVESCENT Fentanyl Citrate for the Management of Breakthrough Pain in Opioid-Tolerant Patients With Chronic Neuropathic Pain
Cephalon, Inc. Frazer, Pennysylvania	A 4-Week, Open-Label Extension Study of ACTIQ (Oral Transmucosal Fentanyl Citrate [OTFC ®] Treatment for Opioid-Tolerant Children and Adolescents with Breakthrough Pain
Cephalon, Inc. Frazer, Pennysylvania	A Multicenter, Open-Label, Long-Term Study of OraVescent®Fentanyl Citrate for the Treatment of Breakthrough Pain in Opioid-Tolerant Cancer Patients

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
Cephalon, Inc. Frazer, Pennysylvania	A Double-Blind, Placebo-Comparison Study to Evaluate the Efficacy and Safety of ACTIQ® (Oral Transmucosal Fentanyl Citrate[OTFC®]) Treatment for Opioid-Tolerant Children and Adolescents with Breakthrough Pain
Cephalon, Inc. Frazer, Pennysylvania	An Open-Label, 12-Month Study to Evaluate the Safety, Tolerability, and Efficacy of ORAVESCENT Fentanyl Citrate for the Management of Breakthrough Pain in Opioid-Tolerant Patients With Chronic Noncancer Pain
Elan Pharmaceuticals Inc. San Diego, California	Elan Protocol ELN92045-205
Grunenthal GmbH, Research and Development Aachen, Germany	Randomized, multicenter, double blind, parallel-group study assessing analgesic efficacy & safety of different dosages of GRT0151Y bid compared to active comparator bid & placebo bid in subjects with chronic knee-joint osteoarthritis
Halozyme Therapeutics, Inc. San Diego, California	Increased Flow Using Subcutaneously Enhanced Morphine (INFUSE-Morphine) Study: A Phase IIIB, double-blind, randomized, crossover study comparing the pharmacokinetics, safety and tolerability of morphine administered subcutaneously with and without human recombinant hyaluronidase (HYLENEX) and intravenously
National Institute on Drug Abuse Bethesda, Maryland	Double-Blind, Placebo-Controlled Assessment of Potential Interactions between Intravenous Methamphetamine and Aripiprazole (NIDA Study MDS-ARIPIP-0001)

Sponsor	Description or Title of Clinical Drug Trial Protocol
Pain Therapeutics, Inc. South San Francisco, California	A Multicenter, Double-Blind, Active- and Placebo-Controlled Efficacy and Safety Study of Oxycodone HCl and Low-Dose Naltrexone HCL (PTI-801) in Patients with Low Back Pain (Pain Therapeutics Protocol PTI-801-XG)
Pain Therapeutics, Inc. South San Francisco, California	A Long-Term, Open-Label, Safety Study of Oxycodone HC1 and Low-Dose Naltrexone HC1 (PTI-801) in Patients with Moderate to Severe Chronic Low Back Pain or with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Hip or Knee
Pain Therapeutics, Inc. South San Francisco, California	A Multicenter, Randomized, Double-Blind, Active- and Placebo-Controlled, Phase III, Efficacy and Safety Study of Oxycodone and Low-Dose Naltrexone (PTI-801) in Patients with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Hip or Knee
PARAXEL International Corp. Waltham, Massachusetts	A Randomized, Double-Blind Comparison of Atomoxetine, Augmented with either Extended-Release Methylphenidate (Concerta™) or Placebo in Children with Attention-Deficit/Hyperactivity Disorder (ADHD) Who Have Not Responded to Stimulant Mono Therapy
Shire Pharmaceutical Dvlpmt., Inc. Rockville, Maryland	A Phase IIIB, Rndmzd, Dbl-Blind, Multi-Ctr, Placebo-Cntrld, Dose-Optzmd, 3-way X-Over Study to Assess the Efficacy, Effect, Tolerability and Safety of 4 & 6 hour Wear Times of Methylphenidate Transderm Sys (MTS) in Pedi Sbjcts aged 6-12 w/ ADHD

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
Shire Pharmaceutical Dvlpmt., Inc. Rockville, Maryland	A Phase III, Multi-Center, Open-label Study of Methylphenidate Transdermal System® (MTS) in Pediatric Patients aged 6-12 with Attention-Deficit/Hyperactivity Disorder (ADHD)
Progenics Pharmaceuticals Tarrytown, New York	A Compassionate Use Study of Methylnaltrexone in Patients with Opioid-Induced Side Effects (Progenics Protocol MNTX 901)
Progenics Pharmaceuticals Tarrytown, New York	A Double-Blind Phase 3, Two-Week, Placebo Controlled Study of Methylnaltrexone (MNTX) for the Relief of Symptomatic Constipation Due to Chronic Opioid Therapy in Advanced Medical Illness; Three-Month Open Label Treatment Extension Option (Progenics Protocol MNTX 302, 302EXT)
Purdue Pharma L.P. Stamford, Connecticut	A Randomized Placebo-Controlled Crossover Trial Evaluating the Effect of Naltrexone at 1, 3, and 6 mg Dose Levels on the Abuse Potential of 40 mg Oxycodone in Non-dependent, Opioid-preferring Subjects
Purdue Pharma L.P. Stamford, Connecticut	Randomized, Double-blind, Multicenter, Active Comparator Study to Determine the Efficacy and Safety of BTDS 20 or Oxy IR®versus BTDS 5 in Subjects with Moderate to Severe Osteoarthritis (OA) Pain
Purdue Pharma L.P. Stamford, Connecticut	A Multicenter, Randomized, Double-blind, Active Comparator Study to Determine the Efficacy and Safety of BTDS 20 or Oxy IR®versus BTDS 5 in Subjects with Moderate to Severe Low Back Pain

Sponsor	Description or Title of Clinical Drug Trial Protocol
Purdue Pharma L.P. Stamford, Connecticut	A Rndmzd, Dbl-Blind, Placebo-Cntrld, Parallel Grp, Multicenter Study to Determine the Efficacy and Safety of Buprenorphine Transdermal System (BTDS) in Subjects with Moderate to Severe Osteoarthritis (OA) Pain Requiring Daily Treatment with Opioids
Shire Pharmaceutical Development Rockville, Maryland	A Phase II, Randomized, Double-blind, Multi-center, Placebo-controlled, Crossover Study of SPD464 in Adults with Attention-Deficit Hyperactivity Disorder (ADHD)
Shire Pharmaceutical Development Rockville, Maryland	A Phase III, Randomized, Double-blind, Multi-center, Placebo-controlled, Parallel-group, Forced Dose Titration, Safety and Efficacy Study of SPD465 in Adults with Attention-Deficit Hyperactivity Disorder (ADHD)
Shire Pharmaceutical Development Rockville, Maryland	A Phase III, Multi-center, Open-label Safety Study of SPD465 in Adults with Attention-Deficit Hyperactivity Disorder (ADHD)
Shire Pharmaceutical Development Rockville, Maryland	A Prospective, Open-Label, Multi-Center Study Evaluating the Safety and Tolerability of Methylphenidate Transdermal System (MTS) in Children Aged 6 - 12 Previously Treated with Extended Release Methylphenidate Product
Solvay Pharmaceuticals, Inc.	Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Efficacy, Safety, and Tolerability Study of Dronabinol MDI in the Acute Treatment of Migraine Headache

Appendix B Cont.

Sponsor	Description or Title of Clinical Drug Trial Protocol
ZARS, Inc. Salt Lake City, Utah	An Open-Label, Long-Term Safety Study to Evaluate the Safety of the ZR02-01 Matrix Transdermal Fentanyl Patch for the Treatment of Osteoarthritis Pain
ZARS, Inc. Salt Lake City, Utah	An Open-Label, Long-Term Safety Study to Evaluate the Safety of the ZR-02-01 Matrix Transdermal Fentanyl Patch for the Treatment of Moderate-to-Severe Cancer Pain
ZARS, Inc. Salt Lake City, Utah	An Open-Label Safety Study to Evaluate the Safety of the ZR-02-01 Matrix Transdermal Fentanyl Patch for the Treatment of Moderate to Severe, Non-malignant Chronic Pain

APPENDIX C

CURRENTLY APPROVED *(December 31, 2005)* RESEARCH STUDIES
ON THE TREATMENT OF CONTROLLED SUBSTANCE ABUSE

Sponsor / PI	Description or Title of Research Study
National Institute on Drug Abuse Bethesda, Maryland	Double-Blind, Placebo-Controlled Trial of Bupropion for the Treatment of Methamphetamine Dependence (NIDA Study CTO-0008)
National Institute on Drug Abuse Bethesda, Maryland	Double-Blind, Placebo-Controlled Assessment of Potential Interactions Between Intravenous Methamphetamine And Aripiprazole (NIDA Study NIDA-MDS-ARIPIP-0001)
National Institute on Drug Abuse Bethesda, Maryland	Single-Blind, Placebo-Controlled Assessment of Potential Interactions Between Intravenous Cocaine, Ethanol and Oral Disulfiram (NIDA Study NIDA-MDS-Disulfiram-001)
Thomas F. Newton, M.D. UCLA/ISAP Clinical Trials Operations 760 Westwood Plaza, Box 12, NPI 175919 Los Angeles, CA 90024	Double-Blind, Randomized, Placebo-Controlled Trial of Rivastigmine (Exelon) as a Potential Medication for Methamphetamine Abuse

APPENDIX D

SECTIONS CONCERNING THE RESEARCH ADVISORY PANEL
FROM THE CALIFORNIA HEALTH AND SAFETY CODE

Sec. 11213. Persons who, under applicable federal laws or regulations, are lawfully entitled to use controlled substances for the purpose of research, instruction, or analysis, may lawfully obtain and use for such purposes such substances as are defined as controlled substances in this division, upon approval for use of such controlled substances in bona fide research, instruction, or analysis by the Research Advisory Panel established pursuant to Sections 11480 and 11481.

Such research, instruction, or analysis shall be carried on only under the auspices of the head of a research project which has been approved by the Research Advisory Panel pursuant to Section 11480 or Section 11481. Complete records of receipts, stocks at hand, and use of these controlled substances shall be kept.

Sec. 11362.9. California Marijuana Research Program; legislative intent; creation; research proposals; establishment; powers and duties; Scientific Advisory Council (In pertinent part)

(d) If the program is administered by the Regents of the University of California any grant research proposals approved by the program shall also require review and approval by the research advisory panel.

(f) All personnel involved in implementing approved proposals shall be authorized as required by Section 11604.

(g) Studies conducted pursuant to this section shall include the greatest amount of new scientific research possible on the medical uses of, and medical hazards associated with, marijuana. The program shall consult with the Research Advisory Panel analogous agencies in other states, and appropriate federal agencies in an attempt to avoid duplicative research and the wasting of research dollars.

Sec. 11374. Every person who violates or fails to comply with any provisions of this division, except one for which a penalty is otherwise in this division specifically provided, is guilty of a misdemeanor punishable by a fine in a sum not less than thirty dollars ($30) nor more than five hundred dollars ($500), or by imprisonment for not less than 15 nor more than 180 days, or by both.

Sec. 11392. Spores or mycelium capable of producing mushrooms or other material which contains psilocyn or psyoclyin may be lawfully obtained and used for bona fide

research, instruction, or analysis, if not in violation of federal law, and if the research, instruction, or analysis is approved by the Research Advisory Panel established pursuant to Sections 11480 and 11481.

Sec. 11478. Marijuana may be provided by the Attorney General to the heads of research projects which have been registered by the Attorney General, and which have been approved by the Research Advisory Panel pursuant to Section 11480.

The head of the approved research project shall personally receipt for such quantities of marijuana and shall make a record of their disposition. The receipt and record shall be retained by the Attorney General. The head of the approved research project shall also, at intervals and in the manner required by the Research Advisory Panel, report the progress or conclusions of the research project.

Sec. 11480. The Legislature finds that there is a need to encourage further research into the nature and effects of marijuana and hallucinogenic drugs and to coordinate research efforts on such subjects.

There is a Research Advisory Panel which consists of a representative of the State Department of Health Services, a representative of the California State Board of Pharmacy, a representative of the Attorney General, a representative of the University of California who shall be a pharmacologist, a physician, or a person holding a doctorate degree in the health sciences, a representative of a private university in this State who shall be a pharmacologist, a physician, or a person holding a doctorate degree in the health sciences, a representative of a statewide professional medical society in this state who shall be engaged in the private practice of medicine and shall be experienced in treating controlled substance dependency, a representative appointed by and serving at the pleasure of the Governor who shall have experience in drug abuse, cancer, or controlled substance research and who is either a registered nurse, licensed pursuant to Chapter 6 (commencing with Section 2700) of Division 2 of the Business and Professions Code, or other health professional. The Governor shall annually designate the private university and the professional medical society represented on the Panel. Members of the Panel shall be appointed by the heads of the entities to be represented, and they shall serve at the pleasure of the appointing power.

The Panel shall annually select a chairman from among its members.

The Panel may hold hearings on, and in other ways study, research projects concerning marijuana or hallucinogenic drugs in this state. Members of the Panel shall serve without compensation, but shall be reimbursed for any actual and necessary expenses incurred in connection with the performance of their duties.

The Panel may approve research projects, which have been registered by the Attorney General, into the nature and effects of marijuana or hallucinogenic drugs, and shall inform the Attorney General of the head of the approved research projects which are entitled to receive quantities of marijuana pursuant to Section 11478.

The Panel may withdraw approval of a research project at any time, and when approval is withdrawn shall notify the head of the research project to return any quantities of marijuana to the Attorney General.

The Panel shall report annually to the Legislature and the Governor those research projects approved by the Panel, the nature of each research project, and, where available, the conclusions of the research project.

Sec. 11481. The Research Advisory Panel may hold hearings on, and in other ways study, research projects concerning the treatment of abuse of controlled substances.

The Panel may approve research projects, which have been registered by the Attorney General, concerning the treatment of abuse of controlled substances and shall inform the chief of such approval. The Panel may withdraw approval of a research project at any time and when approval is withdrawn shall so notify the chief.

The Panel shall, annually and in the manner determined by the Panel, report to the Legislature and the Governor those research projects approved by the Panel, the nature of each research project, and where available, the conclusions of the research project.

Sec. 11603. The Attorney General, with the approval of the Research Advisory Panel, may authorize persons engaged in research on the use and effects of controlled substances to withhold the names and other identifying characteristics of individuals who are the subjects of the research. Persons who obtain this authorization are not compelled in any civil, criminal, administrative, legislative, or other proceedings to identify the individuals who are the subjects of research for which the authorization was obtained.

Sec. 11604. The Attorney General, with the approval of the Research Advisory Panel, may authorize the possession and distribution of controlled substances by persons engaged in research. Persons who obtain this authorization are exempt from state prosecution for possession and distribution of controlled substances to the extent of the authorization.