FORTY-FIRST ANNUAL REPORT

of the

RESEARCH ADVISORY PANEL OF CALIFORNIA

2011

PREPARED FOR THE

LEGISLATURE AND GOVERNOR

RESEARCH ADVISORY PANEL OF CALIFORNIA
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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.

SUMMARY OF 2011 PANEL ACTIVITIES

During 2011 the Panel reviewed forty-three research study submissions. Forty-one were approved by the Panel. Among forty-one approved studies, eleven studies were Academic research studies, three studies were Substance Abuse Treatment research protocols, and twenty-seven studies were Clinical Drug Trial research protocols.

Thirty-seven research studies were completed or, in a few cases, terminated in 2011, and they were closed on the Panel's records.

At the end of 2011, the Panel was monitoring ninety-seven active 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, Significant Adverse Event (SAE) reports and site visits. Approval may be withdrawn if the study deviates significantly from the approved protocol.

Table 1 is a list of the studies approved by the Panel in 2011 and Table 2 is a list of the studies closed by the Panel in 2011.

SELECTED RESEARCH FINDINGS

Below are brief summary reports of several Panel approved projects which are of interest and indicative of the types of controlled substance research projects currently ongoing in California:

Titan Pharmaceuticals has announced positive results of six-month open-label safety retreatment study of probuphine titled "A Phase 3, Six-Month, Open-Label Re-Treatment Study of Probuphine™ in Opioid Addiction"

A total of 85 patients were enrolled at 18 sites with 67 subjects completing treatment. In California, 33 subjects were enrolled, 26 subjects completed the study, and 7 subjects withdrew early.

In this study, Probuphine was shown to be well tolerated, including the implant insertion and removal procedures, with a low incidence of adverse events and overall safety profile similar to that observed in the confirmatory Phase 3 study. Patients also reported a decreased use of illicit opioids, good control of opioid withdrawal and cravings and

high overall satisfaction with Probuphine. These data build upon the positive results of the Probuphine Phase 3 program reported to date and further support the company's preparation of a New Drug Application (NDA) for Probuphine.

Titan also provided an update on the preparation of the NDA for Probuphine, which it now plans to submit in the third quarter of this year. The company is on track to complete its analytical testing of Probuphine to provide additional Chemistry, Manufacturing and Control (CMC) data requested by the U.S. Food and Drug Administration (FDA) along with its preparation of the integrated clinical data, summary reports and electronic document preparation by mid-year. The manufacturing facility expansion and qualification for commercial scale production fo Probuphine is in process, but has been slightly delayed due to longer than expected lead-time on air handling equipment and the manufacturing of three qualification batches is now expected to be completed in September.

Dr. Peggy Compton, RN, PhD, FAAN and colleagues at University of California, Los Angeles have provided the Panel with the following summary of research titled "Pain, Opioids and Pro-inflammatory Immune Responses"

The goal of our study is to evaluate inflammatory and immune responses to pain and/or opiate challenges in prescription opioid abusers (N=22, 11 female) and gender and age-matched healthy controls. To get the study underway and establish study procedures, we obtained UCLA IRB approval (MIRB3) for the healthy control group in June of 2010. To date, of the 163 potential healthy control subjects (78 females) responding to recruitment efforts, 45 (20 females) have been screened and 20 enrolled (9 females).

We submitted an amendment to include buprenorphine-maintained prescription opioid abusers (POAs) in December 2010 and were granted approval to enroll three POAs on May 26, 2011. IRB approval for the remaining eighteen POAs is contingent upon the IRB's satisfaction with the participation report of these initial 3 POAs. Since recruitment efforts began in July of 2011, we've had eight potential POA respondents (2 females), all of whom did not meet the initial eligibility criteria of being an opioid abuser or in a buprenorphine treatment program.

Decreased POA admission rates at the Integrated Substance Abuse Programs clinic was an initial barrier to out POA recruiting efforts. In August of 2011 the IRB approved expansion of our recruitment efforts to include SAMHSA-qualified opioid treatment centers (OTC) and private buprenorphine treatment specialist clinics in the greater Los Angeles area. Despite positive clinician response to our study objectives, we have yet to enroll a POA subject. Our colleagues have cited our exclusion criteria prohibiting participation of subjects with co-morbid DSM-IV diagnoses as a significant barrier to

recruitment; the clinical reality is that the majority of opioid abusers who present to treatment have a dual-diagnosis.
We continue to explore ways to boost recruitment and enrollment. Encouraged by the many positive clinician responses, we remain optimistic that we will reach our target of POAs by August 31, 2012.

Rhodes Pharmaceuticals has reported the status of the study titled "A Randomized, Parallel, Double-Blind Efficacy and Safety study of Biphentin™ Methylphenidate Hydrochloride Extended Release Capsules Compared to Placebo in Children and Adolescents 6 to 18 Years With Attention Deficit Hyperactivity Disorder"

Biphentin™ is designed to be a single, daily dose alternative to separate doses of immediate release methylphenidate by providing an extended release biphasic plasma profile. It distinguishes itself from similar extended release products on the market by achieving a first Cmax more similar to immediate release methylphenidate, which provides clinical advantages. It also comes in more strengths, eight, that allow better individualized dosing. Biphentin® was approved by Health Canada in March 2006 and launched in Canada in August 2006.

One California sate was involved in this multi-center clinical trial at the University of California, Irvine Child Development Center. The UC Irvine site enrolled 29 subjects, and 24 subjects completed the 12-week study. The first subject was enrolled in January 2011. The clinical phase of the study concluded in November 2011.

The protocol provides for continuing compassionate use of the study drug following termination of the 12-week study. Currently approximately 14 patients continue to take the drug, one capsule a day. These patients are being monitored on a periodic basis.

TABLE 1

RESEARCH STUDIES
APPROVED IN 2011

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Hussien Al-Shamma, Ph.D. Arena Pharmaceuticals, Inc. San Diego, CA	Evaluation of lorcaserin for abuse liability using the Drug Discrimination Test in the Rat
Reese T. Jones, M.D. UCSF Drug Dependence Research Center San Francisco, CA	Phase I Study of Interactions between Oral Naltrexone and Bupropion and Intravenous Methamphetamine in Methamphetamine Experienced
Daniel Levin, Ph.D. Norac Pharma Azusa, CA	Evaluation of Cannabinoids derived from the Natural Product Marijuana
Sean Mackey, MD, PhD Stanford University Division of Pain Management Palo Alto, CA	Neural and Immune Effects of Short-term Opioid Use in Chronic Pain Patients
Ardis Ann Moe, M.D. UCLA Center for AIDS Research and Education Los Angeles, CA	Phase III, Placebo-Controlled, Double-Blind Crossover Study of Slow-Release Methylphenidate (Concerta ™) for Treatment of HIV Dementia
Loren H. Parsons, Ph.D. The Scripps Research Institute La Jolla, CA	Cognitive and Neurochemical Effects of Δ9-tetrahydrocannabinol and related cannabinoids in rodents

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Matthew L. Springer, Ph.D. UCSF San Francisco, CA	Assessment of Impairment of Vascular Function in Rats by Environmental Exposure to Marijuana Second Hand Smoke
Michael A. Taffe, Ph.D. The Scripps Research Institute La Jolla, CA	Behavioral and Physiological Toxicities of Cannabinoids
Michael A. Taffe, Ph.D. The Scripps Research Institute La Jolla, CA	Behavioral Toxicities of Amphetamine and Cathinone Stimulant Drugs
Ronald G. Victor, M.D. Cedars-Sinai Medical Center Los Angeles, CA	Cocaine and Sympathetic Nerve Activity in Humans - "Cocaine and the Heart"
Barth Wilsey, M.D. UC Davis Sacramento, CA	The Effect of Vaporized Cannabis on Neuropathic Pain in Spinal Cord Injury
AcelRx Pharmaceuticals Redwood City, CA	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of the Sufentanil NanoTab for the Management of Acute Pain Following Bunionectomy Alone or with Hammertoe Repair (AcelRx SAP202)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
AcelRx Pharmaceuticals Redwood City, CA	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of the Sufentanil NanoTab PCA System/15 mcg for the Treatment of Post-Operative in Patients after Open Abdominal Surgery (AcelRx IAP310)
AcelRx Pharmaceuticals Redwood City, CA	A Multicenter, Randomized, Open-Label, Parallel-Group Trial to Compare the Efficacy and Safety of the Sufentanil NanoTab PCA System/15 mcg to Intravenous Patient-Controlled Analgesia with Morphine for the Treatment of Acute Post-Operative Pain (AcelRx IAP309)
Astra Zeneca / CRO - Quintiles Overland Park, KS	A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of NKTR-118 in Patients with Non-Cancer-Related Pain and Opioid-Induced Constipation (OIC) (AstraZeneca D3820C00004)
Astra Zeneca / CRO - Quintiles Overland Park, KS	A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of NKTR-118 in Patients with Non-Cancer-Related Pain and Opioid-Induced Constipation (OIC) (AstraZeneca D3820C00005)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Astra Zeneca / CRO - Quintiles Overland Park, KS	A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of NKTR-118 in Relieving Opioid-Induced Constipation (OIC) in Patients with Cancer-Related Pain (AstraZeneca D3820C00006)
Astra Zeneca / CRO - Quintiles Overland Park, KS	A Randomized, Double-Blind, Placebo-Controlled 12-Week Extension Study to Assess the Safety and Tolerability of NKTR-118 in Patients with Non-Cancer-Related Pain and Opioid-Induced Constipation (OIC) (AstraZeneca D3820C00007)
Astra Zeneca / CRO - Quintiles Overland Park, KS	An Open-Label 52 week Study to Assess the Long-Term Safety of NKTR-118 in Opioid-Induced Constipation (OIC) in Patients with Non-Cancer-Related Pain (AstraZeneca D3820C00008)
Astra Zeneca / CRO - Quintiles Overland Park, KS	An Open-label, Parallel-group, Phase I Study to Compare the Pharmacokinetics of NKTR-118 Following a Single-Oral Dose in Subjects with Renal Impairment and Subjects with Normal Renal Function (AstraZenica D3820C00009)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Johnson & Johnson PRD Malvern, PA	A Single-Dose, Open-Label, Randomized, Four-Way Crossover Study to Assess the Dose-Proportionality of the Pharmacokinetics of Tapentadol, Given as Tamper-Resistant Tablets, in Healthy Japanese and Korean Male Subjects (J & J PAI 1064)
Mallinckrodt Inc / CRO - INC Middleton, WI	An Open Label Safety Study of COV795 in Subjects with Osteoarthritis or Chronic Low Back Pain (COV 15000181US)
Mallinckrodt Inc. Hazelwood, MD	A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Evaluation of the Safety and Analgesic Efficacy of COV795 (Oxycodone HCl / Acetaminophen) ER Tablets in Moderate to Severe Post-Operative Bunionectomy Pain Followed by an Open Label Extension (COV 15000182US)
Mundipharma / CRO - Parexel Woburn, MA	A Confirmatory, Placebo-Controlled, Randomized, Double-Blind, Single-Dummy, Parallel Group, Ratio-Finding Study in Constipated Pain Patients to Establish an Optimal Hydromorphone (Mundipharma HMX 3501)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Novartis Pharmaceuticals East Hanover, NJ	A 6-Month, Open-Label Extension to a 40-Week, Randomized, Double-Blind, Placebo-Controlled, Multicenter Efficacy and Safety study of Ritalin® LA in the Treatment of Adult Patients with Childhood-Onset ADHD (Novartis CRIT 124D 2302E1)
Purdue / CRO - PRA Raleigh, NC	A Randomized, Double-blind, Placebo-controlled, Multicenter Trial with an Enriched Study Design to Assess the Efficacy and Safety of Oxycodone/Naloxone Controlled-release Tablets (OXN) Compared to Placebo in Opioid-experienced Subjects with Moderate to Severe Pain due to Chronic Low Back Pain who Require Around-the-clock Opioid Therapy (Purdue ONU3701)
Purdue / CRO - Quintiles Overland Park, KS	A Randomized, Double-blind, Double-dummy, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Trial of Oxycodone Naloxone Controlled-release Tablets (OXN) to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-induced Constipation (Compared to Oxycodone Controlled-release Tablets (OXY) in Opioid-experienced Subjects with Uncontrolled Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation who Require Around-the-clock Opioid Therapy (Purdue ONU3704)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Purdue / CRO - Quintiles Overland Park, KS	A Randomized, Double-blind, Double-dummy, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Trial of Oxycodone/Naloxone Controlled-release Tablets OXN) to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-induced Constipation (Compared to Oxycodone Controlled-release Tablets (OXY) in Opioid-experienced Subjects with Controlled Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation with Require Around-the-clock Opioid Therapy (Purdue ONU3705)
Purdue / CRO - INC Raleigh, NC	An Open-label, Multicenter Study to Assess the Long-Term Safety of Hydrocodone Bitartrate (HYD) Tablets 20 to 120 mg Once-daily in Subjects with Moderate to Severe Chronic Non-malignant and Non-neuropathic Pain (Purdue HYD3003)
Purdue / CRO - PRA Charlottesville, VA	An Open-label, Extension Study to Assess the Long-Term Safety of Twice Daily Oxycodone Hydrochloride Controlled-release Tablets in Opioid Experienced Children Who Completed the OTR3001 Study (Purdue OTR3002)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Purdue / CRO - INC Raleigh, NC	A Multicenter, Randomized, Double-blind, Placebo-controlled Study with an Open-label Run-in to Assess the Efficacy and Safety of Hydrocodone Bitartrate (HYD) Tablets 20 to 120 mg Once-daily in Subjects with Moderate to Severe Chronic Low Back Pain (Purdue HYD3002)
Roxane / CRO - Quintiles Durham, NC	A Multicenter, Open Label, Safety and Pharmacokinetic Study of Oral Morphine Sulfate Administration in Pediatric Subjects 2 years old through 17 years old with Postoperative Pain (Roxane MORP-OS+T-(2-17)-SPK-1)
Shire / CRO - Premier Research Bluff City, TN	A Phase 2, Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Forced-Dose Titration Study to Evaluate the Efficacy, Safety, and Tolerability of SPD489 in Adults Aged 18-55 Years with Binge Eating Disorder (Shire SPD489-208)
Shire / CRO - ICON Brentwood, TN	Phase 3, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Flexible Dose Titration, Efficacy and Safety Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant (Shire SPD489-322)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Shire / CRO - ICON Brentwood, TN	Phase 3, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Flexible Dose Titration, Efficacy and Safety Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant (Shire SPD489-323)
Shire / CRO - ICON Brentwood, TN	Phase 3, Open-label, Multicenter, 12-month Extension Safety and Tolerability Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Residual Symptoms or Inadequate Response Following Treatment with an Antidepressant (Shire SPD489-329)
Shire Pharmaceuticals Wayne, PA	A Phase 1, Randomized, Double-blind, Placebo-controlled Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Ascending, Multiple Oral Doses of SPD489 (Lisdexamfetamine Dimesylate) in Clinically Stable Adults with Schizophrenia (Shire SPD489-119)

Table 1 Cont.

PI / Sponsor	Title of Study / Clinical Drug Trial Protocol
Shire Pharmaceuticals Wayne, PA	A Phase 2, Multicenter, Double-blind, Parallel-group, Randomized, Placebo-controlled, Forced-dose Titration, Dose-ranging Efficacy and Safety Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant (Shire SPD 489-209)
Lara Ray, Ph.D. UCLA Los Angeles, CA	Pharmacogenetics of Naltrexone for Methamphetamine Use Disorder
Steve Shoptaw, Ph.D. UCLA Dept of Family Medicine Los Angeles, CA	Varenicline for Methamphetamine Dependence
NIDA Rockville, MD	Cocaine Use Reduction with Buprenorphine (CURB) (NIDA CTN-0048)

TABLE 2

RESEARCH STUDIES CLOSED OR
CANCELLED IN 2011

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Gayle C. Baldwin, Ph.D. UCLA Los Angeles, CA	Methamphetamine Dependence: A Novel Laboratory Model
Giovanni Cucchiaro, MD Childrens Hospital Los Angeles USC Keck School of Medicine Los Angeles, CA	Caudal versus Intrathecal Morphine for Post-operative Pain Control in Pediatric Patients
G. Patrick Dauert, M.D. UC Davis Medical Center Sacramento, CA	Does Oral Methadone Use in Opiate Replacement Therapy Prolong the QTc Interval?
Robert H. Edwards, M.D. Departments of Neurology and Physiology UCSF School of Medicine San Francisco, CA	Role of glutamate release by monoamine neurons
Frederick D. Frankel, Ph.D. UCLA Los Angeles, CA	Social Skills Training for Medicated Children
Jean Gehricke, Ph.D. UC Irvine Irvine, CA	The Reinforcing Mechanisms of Smoking in Adult ADHD

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Ian Gibbons, Ph.D. Theranos, Inc. Palo Alto, CA	Assay Development for Medical Device Submission to FDA
Scott Irwin, MD, PhD San Diego Hospice and Institute for Palliative Medicine San Diego, CA	An Open Label Trial of Methylphenidate for The Rapid Treatment of Depression in Hospice Patients
Thomas S. Kilduff, Ph.D. SRI International Menlo Park, CA	Neurobiological Studies of Gammahydroxybutyrate (GHB)
Thomas King, Ph.D. Alexza Pharmaceuticals Mt. View, CA	Development of an FDA Approved Dronabinol Pharmaceutical Product for Inhalation Delivery
Yuriy Kirichok, Ph.D. UCSF San Francisco, CA	Effects of Cannabinoids on Sperm Activity and Fertility
Edward T. Kisak, Ph.D. Fqubed, Inc. San Diego, CA	Transdermal Delivery of Tetrahydrocannabinol
Kimberly D. Lakes, Ph.D. UC Irvine Irvine, CA	The Effects of Vyvanse on Brain Hemodynamics and Reading

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Stanley Parsons, Ph.D. UC Santa Barbara Santa Barbara, CA	Rapid Detection of 4-hydroxybutyrate
Mark Rollins, MD, PhD UCSF San Francisco, CA	Supplemental Oxygen: A Reduction in Pulse Oximetry Sensitivity or an Increased Margin of Safety?
Cephalon, Inc. Fort Washington, PA	A 12-Week, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Hydrocodone Bitartrate Extended-Release Tablets (CEP-33237) at 15 to 90 mg Every 12 Hours for Relief of Moderate to Severe Pain in Patients with Osteoarthritis or Low Back Pain Who Require Opioid Treatment for an Extended Period of Time (Cephalon C33237/3079).
Cephalon, Inc. Fort Washington, PA	A 12-Month, Open-Label Study to Evaluate the Long-Term Safety of Hydrocodone Bitartrate Extended-Release Tablets (CEP-33237) at 15 to 90mg Every 12 Hours in Patients Who Require Opioid Treatment for an Extended Period of Time (Cephalon C33237/3080)
Eli Lilly Pharmaceuticals Indianapolis, IN	A Fixed-Dose, Randomized, Double-Blind, Placebo-Controlled Study of LY2216684 in Pediatric Patients with Attention Deficit/Hyperactivity Disorder (Lilly H9P-MC-LNBF)

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Insys Therapeutics Phoenix, AZ	A Randomized, Double-Blind, Placebo-Controlled Multi-Center Study to Evaluate the Safety and Efficacy of Fentanyl Sublingual Spray (Fentanyl SL Spray) for the Treatment of Breakthrough Cancer Pain (Insys INS-05-001)
Ortho-McNeil Janssen Scientific Affairs Titusville, NJ	A Placebo-controlled, Double-blind, Parallel-group, Individualized Dosing Study Optimizing Treatment of Adults with Attention Deficit Hyperactivity Disorder to an Effective Response with OROS Methylphenidate (OMJSA CONCERTA-ATT-3014)
Johnson & Johnson PRD Horsham, PA	An Open-Label, Single-Ascending-Dose Study to Investigate the Pharmacokinetics and Safety of CONCERTA® in Healthy Japanese Adult Male Subjects (J&J CONCERTANAP1003)
Johnson & Johnson PRD Titusville, NJ	A Randomized, Double-Blind, Placebo- and Active-Controlled Study to Evaluate the Efficacy, Safety and Tolerability of JNJ-42160443 as Monotherapy in Subjects with Moderate to Severe, Chronic Knee pain from Osteoarthritis (J & J PRD JNJ-42160443-PAI-2006)

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
King Pharmaceuticals Cary, NC	A Multi-center, Primary Care-Based, Open-Label Study to Assess the Success of Converting Opioid-Experienced Patients, with Chronic, Moderate to Severe Pain, to EMBEDA™ Using a Standardized Conversion Guide, and to Identify Behaviors Related to Prescription Opioid Abuse, Misuse, and Diversion (King ALO-01-10-4003)
Neuromed Pharmaceuticals Conshohocken, PA	A Phase III, Flexible-Dose Titration Followed by a Randomized Double-Blind Study of Controlled-Release OROS® Hydromorphone HCl (NMED-1077) Compared to Placebo in Patients with Osteoarthritis Pain (Neuromed NMT1077-302)
Novartis Pharmaceuticals East Hanover, NJ	A randomized, multi-center, double-blind, placebo-controlled, cross-over study evaluating the safety and efficacy of Focalin-XR 30 mg vs Focalin XR 20 mg as measured by SKAMP-Combined scores in children with Attention-Deficit Hyperactivity Disorder (ADHD) in a laboratory classroom setting (Novartis CRIT 124 EUS 21)

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Ortho-McNeil Janssen Scientific Affairs Irvine, CA	Double-Blind, Randomized, Placebo-Controlled, Crossover Study Evaluating the Academic, Behavioral and Cognitive Effects of CONCERTA on Older Children with ADHD (The ABC Study) (OMJSA CONCERTA-ATT-4069)
Ortho-McNeil Janssen Scientific Affairs Raritan, NJ	A Randomized, Double-Blind, Multi-Center, Parallel-Group Study of Tapentadol Immediate Release (IR) vs. Oxycodone IR for the Treatment of Subjects with Acute Post-Operative Pain Following Elective Arthroscopic Shoulder Surgery (OMJSA R331333-PAI-3022)
QRxPharma / CRO - Rho, Inc. Chapel Hill, NC	A Double-Blind, Randomized, Multi-Center, Repeat-Dose, Comparison of the Analgesic Efficacy & Safety of the Opioid Combination Q8003 to each of the Individual Milligram Components (Oxycodone & Morphine) in the Management of Acute Moderate to Severe Pain Following Bunionectomy Surgery (QRxPharma Q8003-021)

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
QRxPharma / CRO - Rho, Inc. Chapel Hill, NC	A Randomized, Double-Blind, Multicenter, Repeat-Dose Comparison of Q8003 to the Morphine-Equivalent Doses of Oxycodone and of Morphine for the Opioid-Related Adverse Events of Nausea, Emesis, and Dizziness in Subjects with Acute Moderate-to-Severe Postoperative pain Following Bunionectomy Surgery (QRxPharma Q8003-022)
Shire / CRO - INC Raleigh, NC	A Phase II, Multicenter Study with Open-label and Randomized Double-blind Placebo-Controlled Withdrawal Phases to Evaluate the Efficacy, Safety, and Tolerability of SPD489 in Adults with Schizophrenia and Predominant Negative Symptoms Who Are Clinically Stable and Taking Stable Doses of Atypical Antipsychotic Medication (Shire SPD489-204)
Shire / CRO - INC Raleigh, NC	A Phase 2, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy, Safety, and Tolerability of SPD489 in Adults with Clinically Significant, Persistent Executive Function Impairments (EFI) and Partial or Full Remission of Recurrent Major Depressive Disorder (Shire SPD-205)

Table 2 Cont.

Sponsor / PI	Title of Study / Clinical Drug Trial Protocol
Zogenix, Inc. Emeryville, CA	A Randomized Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy, Tolerability and Safety of Hydrocodone Bitartrate Controlled-Release Capsules in Opioid-experienced Subjects with Moderate to Severe Chronic Low Back Pain. (Zogenix ZX002-0801)
Gantt Galloway, Pharm.D. APRL CPMC Research Institute San Francisco, CA	A Dose Ranging Study of Guanfacine for Methamphetamine
Walter Ling, M.D. UCLA Los Angeles, CA	Optimizing Outcomes Using Suboxone for Opiate Dependence
Catalyst Pharmaceuticals Coral Gables, FL	Vigabatrin for Treatment of Cocaine Dependence: A Phase II Study" (Catalyst CPP-01005)
Catalyst Pharmaceuticals Coral Gables, FL	Vigabatrin for Treatment of Methamphetamine Dependence: A Phase II Study (Catalyst CPP-02001)
Titan Pharmaceuticals S. San Francisco, CA	A Phase 3, Six-Month, Open-Label Re-Treatment Study of Probuphine in Opioid Addiction (Titan PRO-811)

APPENDIX A

CURRENTLY OPEN *(through December 31, 2011)*
SCHEDULE I AND SCHEDULE II
NON-HUMAN AND ACADEMIC HUMAN
RESEARCH STUDIES

Principal Investigator	Title of Study
Mark A. Agius, M.D. UC. Davis Davis, CA	Cannabis for Spasticity/Tremor in MS: Placebo Controlled Study
Hussien Al-Shamma, Ph.D. Arena Pharmaceuticals San Diego, CA	Evaluation of lorcaserin for abuse liability using the Drug Discrimination Test in the Rat
Danilyn Angeles, Ph.D. Loma Linda University Loma Linda, CA	Panel Approved Research
Mariusz Banaszczyk, Ph.D. Biosite Diagnostics San Marcos, CA	Development of In-vitro Immunoassays for the Detection of Abused Substances
Selena E. Barrett, Ph.D. Ernest Gallo Clinic & Research Ctr. Emeryville, CA	The role of cannabinoids and ibogaine in the treatment of alcoholism and drug addiction
Matthias Behrends, M.D. UCSF San Francisco, CA	A Randomized, Parallel, Double-Blind Efficacy and Safety Study of Biphentin™ Methylphenidate Hydrochloride Extended Release Capsules Compared to Placebo in Children and Adolescents 6 to 18 years with Attention Deficit Hyperactivity Disorder

Appendix A Cont.

Principal Investigator	Title of Study
Nancy E. Buckley, Ph.D. California State Polytechnic Univ. Pomona, CA 91768	Panel approved research
John R. Cashman, Ph.D. Human BioMolecular Research Institute San Diego, CA	Molecular Evolution of Human Cocaine Catalysis
Kent S. Chu, Ph.D. YJ Bio-Products Cordova, CA	Immunochromatographic Test Device for THC and LSD
Laura Colin Biostride, Inc. Redwood City, CA	Panel Approved Research Project
Peggy Compton, RN, PhD UCLA School of Nursing Los Angeles, CA	Pain, Opioids, and Pro-inflammatory Immune Responses
Mark Geyer, Ph.D. UC San Diego San Diego, CA	Behavioral and Cytoflourimetric Studies of Psychoactive Drugs in Rats
Valerie Gruber, Ph.D. UCSF SF General Hospital San Francisco, CA	Investigation of Age Differences in Analgesic, Cognitive, and subjective effects of Oxycodone, Hydrocodone, and Acetaminophen
Kanthi F. Hettiarachchi, Ph.D. SRI International Menlo Park, CA	Analysis of Cannabinoids

Principal Investigator	Title of Study
Scott A. Irwin, MD, PhD San Diego Hospice/ Palliative Care San Diego, CA	Panel Approved Research Project
Reese Jones, M.D. UCSF San Francisco, CA	Phase I Study of Interactions between Oral Naltrexone and Bupropion and Intravenous Methamphetamine in Methamphetamine Experienced
Adam Leventhal, Ph.D. USC Keck School of Medicine Alhambra, CA	Influence of Genes and Emotions on medication Effects
Daniel Levin, Ph.D. NORAC Pharma Azusa, CA	Panel Approved Research
Daniel Levin, Ph.D. NORAC Pharma Azusa, CA	Panel Approved Research
Daniel Levin, Ph.D. NORAC Pharma Azusa, CA	Panel Approved Research
Daniel Levin, Ph.D. NORAC Pharma Azusa, CA	Panel Approved Research
Marie Lin, Ph.D. R.Ph. Lin-Zhi International, Inc. Sunnyvale, CA	Lin-Zhi Immunoassay Development Study

Appendix A Cont.

Principal Investigator	Title of Study
Edythe London, Ph.D. UCLA Los Angeles, CA	A Study to Assess the Cardiovascular, Cognitive, and Subjective Effects of Atomoxetine in Combination with Intravenous Amphetamine
Sean Mackey, MD, PhD Stanford University Palo Alto, CA	Neural and Immune Effects of Short-term Opioid Use in Chronic Pain Patients
Sean D. McAllister, Ph.D. CPMC Research Institute San Francisco, CA	Panel Approved Research Project
James T. McCracken, M.D. UCLA NPI Los Angeles, CA	An 8-Week, Randomized, Double-Blind Comparison of Twice-Daily Guanfacine, Once-Daily d-Methylphenidate ER (Focalin XR) and the Combination, with a 12 Month Open-Label Extension for the Treatment of ADHD in Pediatric Subjects Aged 7 to 14 years
John Mendelson, M.D. APRL/CPMC Research Institute San Francisco, CA	The Effects of MDMA on Sleep Architecture, Water Homeostasis, and Cognitive Function
John Mendelson, M.D. APRL/CPMC Research Institute San Francisco, CA	Bioavailability and Urinary Excretion of Oral L-Methamphetamine
Ardis Moe, Ph.D. UCLA Center for AIDS Research Los Angeles, CA	Phase III, Placebo-Controlled, Double-Blind Crossover Study of Slow-Release Methylphenidate (Concerta ™) for Treatment of HIV Dementia

Principal Investigator	Title of Study
Loren Parsons, Ph.D. The Scripps Research Institute La Jolla, CA	Cognitive and Neurochemical Effects of Δ9-tetrahydrocannabinol and related cannabinoids in rodents
Richard Reznichek, M.D. Harbor-UCLA Medical Center Torrance, CA	A prospective, randomized, double-blind study comparing the efficacy and safety of intra nasal fentanyl spray to placebo as an analgesic in patients undergoing outpatient cystoscopic procedures
Rajkumar J. Sevak, Ph.D. UCLA Los Angeles, CA	Human Methamphetamine Self-Administration in a Progressive-Ratio Paradigm
Rajkumar J. Sevak, Ph.D. UCLA Los Angeles, CA	Safety and Initial Efficacy of Lisdexamfetamine for Modifying the Behavioral Effects of Intravenous Methamphetamine in Humans
Matthew L. Springer, Ph.D. UCSF San Francisco, CA	Assessment of Impairment of Vascular Function in Rats by Environmental Exposure to Marijuana Second Hand Smoke
Michael Taffe, Ph.D. The Scripps Research Institute La Jolla, CA	Behavioral and Physiological Toxicities of Cannabinoids
Michael Taffe, Ph.D. The Scripps Research Institute La Jolla, CA	Behavioral Toxicities of Amphetamine and Cathinone Stimulant Drugs

Appendix A Cont.

Principal Investigator	Title of Study
Stephen Van Dien, Ph.D. Genomatica, Inc. San Diego, CA	Panel Approved Research Project
Ronald Victor, M.D. Heart Institute Cedars-Sinai Medical Center Los Angeles, CA	Cocaine and Sympathetic Nerve Activity in Humans - "Cocaine and the Heart"
Mark Wallace, M.D. UC San Diego San Diego, CA	Efficacy of Inhaled Cannabis for the Treatment of Painful Diabetic Peripheral Neuropathy
Jennifer L. Whistler, Ph.D. Ernest Gallo Clinic & Research Ctr. Emeryville, CA	Endocytosis and Opioid Receptors
Timothy Wigal, Ph.D. UC Irvine Irvine, CA	Brain Dopamine Function in Adults with Attention Deficit/Hyperactivity Disorder (ADHD)
Barth Wilsey, M.D. UC Davis Medical Center Sacramento, CA	The Analgesic Effect of Vaporized Cannabis on Neuropathic Pain
Barth Wilsey, M.D. UC Davis Medical Center Sacramento, CA	The Effect of Vaporized Cannabis on Neuropathic Pain in Spinal Cord Injury

APPENDIX B

CURRENTLY OPEN *(through December 31, 2011)*
SCHEDULE II CLINICAL DRUG TRIAL STUDIES

Sponsor	Description or Title of Clinical Drug Trial Protocol
AcelRx Redwood City, CA	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of the Sufentanil NanoTab for the Management of Acute Pain Following Bunionectomy Alone or with Hammertoe Repair (AcelRx SAP202)
AcelRx Redwood City, CA	A Multicenter, Randomized, Double-Blind, Placebo-Controlled Trial to Evaluate the Efficacy and Safety of the Sufentanil NanoTab PCA System/15 mcg for the Treatment of Post-Operative in Patients after Open Abdominal Surgery (AcelRx IAP310)
AcelRx Redwood City, CA	A Multicenter, Randomized, Open-Label, Parallel-Group Trial to Compare the Efficacy and Safety of the Sufentanil NanoTab PCA System/15 mcg to Intravenous Patient-Controlled Analgesia with Morphine for the Treatment of Acute Post-Operative Pain (AcelRx IAP309)
Astra Zenica / CRO - Quintiles Overland Park, KS	A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of NKTR-118 in Patients with Non-Cancer-Related Pain and Opioid-Induced Constipation (OIC) (AstraZeneca D3820C00004)

Sponsor	Description or Title of Clinical Drug Trial Protocol
Astra Zenica / CRO - Quintiles Overland Park, KS	A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of NKTR-118 in Patients with Non-Cancer-Related Pain and Opioid-Induced Constipation (OIC) (AstraZeneca D3820C00005)
Astra Zenica / CRO - Quintiles Overland Park, KS	A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of NKTR-118 in Relieving Opioid-Induced Constipation (OIC) in Patients with Cancer-Related Pain (AstraZeneca D3820C00006)
Astra Zenica / CRO - Quintiles Overland Park, KS	A Randomized, Double-Blind, Placebo-Controlled 12-Week Extension Study to Assess the Safety and Tolerability of NKTR-118 in Patients with Non-Cancer-Related Pain and Opioid-Induced Constipation (OIC) (AstraZeneca D3820C00007)
Astra Zenica / CRO - Quintiles Overland Park, KS	An Open-Label 52 week Study to Assess the Long-Term Safety of NKTR-118 in Opioid-Induced Constipation (OIC) in Patients with Non-Cancer-Related Pain (AstraZeneca D3820C00008)
Astra Zenica / CRO - Quintiles Overland Park, KS	An Open-label, Parallel-group, Phase I Study to Compare the Pharmacokinetics of NKTR-118 Following a Single-Oral Dose in Subjects with Renal Impairment and Subjects with Normal Renal Function (AstraZenica D3820C00009)

Sponsor	Description or Title of Clinical Drug Trial Protocol
BRC Operations Pty Ltd. Ultimo, NSW, Australia	International Study to Predict Optimized Treatment in Attention Deficit/.Hyperactivity Disorder (BRC iSPOT-A)
GW Pharmaceuticals Mill Valley, CA	Panel Approved Research Project
GW Pharmaceuticals Milly Valley, CA	Panel Approved Research Project
GW Pharmaceuticals Milly Valley, CA	Panel Approved Research Project
INTRuST Clinical Consortium La Jolla, CA	Randomized Controlled Trial of Galantamine, Methylphenidate, and Placebo for the Treatment of Cognitive Symptoms in Patients with Mild Traumatic Brain Injury (mTBI) and/or Posttraumatic Stress Disorder (PISD) ["Cognitive REmediation After Trauma Exposure" Trial = CREATE Trial"]
Johnson & Johnson Titusville, NJ	A Randomized-Withdrawal, Placebo-Controlled, Study Evaluating the Efficacy, Safety, and Tolerability, of Tapentadol Extended-Release (ER) in Subjects with Chronic, Painful Diabetic Peripheral Neuropathy (DPN) (J&J R331333-PAI-3027)

Sponsor	Description or Title of Clinical Drug Trial Protocol
Johnson & Johnson Malvern, PA	A Single-Dose, Open-Label, Randomized, Two-Way Crossover Study to Assess the Bioequivalence of Tapentadol Give as Two 25mg Extended-Release Tamper-Resistant Formulation (TRF) Tablets Relative to One 50mg Extended-Release TRF Tablet in Healthy Japanese Male Subjects (J & J R331333 PAI 1062)
Johnson & Johnson Malvern, PA	A Single-Dose, Open-Label, Randomized, Two-Way Crossover Study to Assess the Bioequivalence of Tapentadol Given as Two 50mg Extended-Release Tamper-Resistant Formulation (TRF) Tablets Relative to One 100mg Extended-Release TRF Tablet in Healthy Japanese Male Subjects (J & J R331333 PAI 1063)
Johnson & Johnson Malvern, PA	A Single-Dose, Open-Label, Randomized, Four-Way Crossover Study to Assess the Dose-Proportionality of the Pharmacokinetics of Tapentadol, Given as Tamper-Resistant Tablets, in Healthy Japanese and Korean Male Subjects (J & J PAI 1064)
Mallinckrodt / CRO - INC Middleton, MD	An Open Label Safety Study of COV795 in Subjects with Osteoarthritis or Chronic Low Back Pain (COV 15000181US)

Sponsor	Description or Title of Clinical Drug Trial Protocol
Mallinckrodt Hazelwood, MD	A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Evaluation of the Safety and Analgesic Efficacy of COV795 (Oxycodone HCl / Acetaminophen) ER Tablets in Moderate to Severe Post-Operative Bunionectomy Pain Followed by an Open Label Extension (COV15000182US)
Mundipharma / CRO - Parexel Woburn, MA	A Confirmatory, Placebo-Controlled, Randomized, Double-Blind, Single-Dummy, Parallel Group, Ratio-Finding Study in Constipated Pain Patients to Establish an Optimal Hydromorphone (Mundipharma HMX 3501)
Novartis Pharmaceuticals East Hanover, NJ	A 40-Week, Randomized, Double-Blind, Placebo controlled, Multicenter Efficacy and Safety Study of Ritalin® LA in the Treatment of Adult Patients with Childhood-Onset ADHD (Novartis CRIT124D2302)
Novartis Pharmaceuticals East Hanover, NJ	A 6-Month, Open-Label Extension to a 40-Week, Randomized, Double-Blind, Placebo-Controlled, Multicenter Efficacy and Safety study of Ritalin® LA in the Treatment of Adult Patients with Childhood-Onset ADHD (Novartis CRIT 124D 2302E1)

Sponsor	Description or Title of Clinical Drug Trial Protocol
Purdue / CRO - PRA Lenexa, KS	An Open-Label Study to Characterize the Pharmacokinetics and Safety of Oxycodone HCl q12h Controlled-Release (ORF) Tablets in Pediatric Patients Aged 6 to 16 Years Inclusive, Who Require Opioid Analgesia (Purdue OTR 1020)
Purdue / CRO - PRA Lenexa, KS	An Open-Label, Multicenter Study of the Safety of Twice Daily Oxycodone HCl Controlled-Release Tablets in Opioid Experienced Children from Ages 6 to 16 Years Old, Inclusive, with Moderate to Severe Malignant and/or Nonmalignant Pain Requiring Opioid Analgesics (Purdue OTR 3001)
Purdue / CRO - PRA Raleigh, NC	A Randomized, Double-blind, Placebo-controlled, Multicenter Trial with an Enriched Study Design to Assess the Efficacy and Safety of Oxycodone/Naloxone Controlled-release Tablets (OXN) Compared to Placebo in Opioid-experienced Subjects with Moderate to Severe Pain due to Chronic Low Back Pain who Require Around-the-clock Opioid Therapy (Purdue ONU3701)

Sponsor	Description or Title of Clinical Drug Trial Protocol
Purdue / CRO - Quintiles Overland Park, KS	A Randomized, Double-blind, Double-dummy, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Trial of Oxycodone Naloxone Controlled-release Tablets (OXN) to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-induced Constipation (Compared to Oxycodone Controlled-release Tablets (OXY) in Opioid-experienced Subjects with Uncontrolled Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation who Require Around-the-clock Opioid Therapy (Purdue ONU3704)
Purdue / CRO - Quintiles Overland Park, KS	A Randomized, Double-blind, Double-dummy, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Trial of Oxycodone/Naloxone Controlled-release Tablets OXN) to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-induced Constipation (Compared to Oxycodone Controlled-release Tablets (OXY) in Opioid-experienced Subjects with Controlled Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation with Require Around-the-clock Opioid Therapy (Purdue ONU3705)
Purdue / CRO - INC Raleigh, NC	An Open-label, Multicenter Study to Assess the Long-Term Safety of Hydrocodone Bitartrate (HYD) Tablets 20 to 120 mg Once-daily in Subjects with Moderate to Severe Chronic Non-malignant and Non-neuropathic Pain (Purdue HYD3003)

Sponsor	Description or Title of Clinical Drug Trial Protocol
Purdue / CRO - PRA Charlottesville, VA	An Open-label, Extension Study to Assess the Long-Term Safety of Twice Daily Oxycodone Hydrochloride Controlled-release Tablets in Opioid Experienced Children Who Completed the OTR3001 Study (Purdue OTR3002)
Purdue / CRO - INC Raleigh, NC	A Multicenter, Randomized, Double-blind, Placebo-controlled Study with an Open-label Run-in to Assess the Efficacy and Safety of Hydrocodone Bitartrate (HYD) Tablets 20 to 120 mg Once-daily in Subjects with Moderate to Severe Chronic Low Back Pain (Purdue HYD3002)
Rhodes Pharmaceuticals Boston, MA	A Randomized, Double-Blind Study of the Time Course of Response of Biphentin® Methylphenidate Hydrochloride Extended Release Capsules As Compared to Placebo in Children 6 to 12 Years With Attention Deficit Hyperactivity Disorder in an Analog Classroom Setting (Rhodes RP-BP-EF001)
Rhodes Pharmaceuticals Boston, MA	A Randomized, Parallel, Double-Blind Efficacy and Safety Study of Biphentin™ Methylphenidate Hydrochloride Extended Release Capsules Compared to Placebo in Children and Adolescents 6 to 18 years with Attention Deficit Hyperactivity Disorder (Rhodes RP-BP-EF002)

Sponsor	Description or Title of Clinical Drug Trial Protocol
Roxane / CRO - Quintiles Durham, NC	A Multicenter, Open Label, Safety and Pharmacokinetic Study of Oral Morphine Sulfate Administration in Pediatric Subjects 2 years old through 17 years old with Postoperative Pain (Roxane MORP-OS+T-(2-17)-SPK-1)
Shire Pharmaceuticals Hampshire, UK	A Phase III, Double-Blind, Placebo-Controlled, Randomized Withdrawal, Multicenter, Extension, Safety and Efficacy Study of Lisdexamfetamine Dimesylate (LDX) in Children and Adolescents Aged 6-17 with Attention-Deficit/Hyperactivity Disorder (ADHD) (Shire SPD489-326)
Shire Pharmaceuticals Wayne, PA	A Phase 2, Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy, Safety, and Tolerability of SPD489 in Adults with Clinically Significant, Persistent Executive Function Impairments (EFI) and Partial or Full Remission of Recurrent Major Depressive Disorder (Shire SPD-205)
Shire / CRO - Premier Buff City, TN	A Phase 2, Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Forced-Dose Titration Study to Evaluate the Efficacy, Safety, and Tolerability of SPD489 in Adults Aged 18-55 Years with Binge Eating Disorder (Shire SPD489-208)

Sponsor	Description or Title of Clinical Drug Trial Protocol
Shire / CRO - ICON Brentwood, TN	Phase 3, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Flexible Dose Titration, Efficacy and Safety Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant (Shire SPD489-322)
Shire / CRO - ICON Brentwood, TN	Phase 3, Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Flexible Dose Titration, Efficacy and Safety Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant (Shire SPD489-323)
Shire / CRO - ICON Brentwood, TN	Phase 3, Open-label, Multicenter, 12-month Extension Safety and Tolerability Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Residual Symptoms or Inadequate Response Following Treatment with an Antidepressant (Shire SPD489-329)

Sponsor	Description or Title of Clinical Drug Trial Protocol
Shire Pharmaceuticals Wayne, PA	A Phase 1, Randomized, Double-blind, Placebo-controlled Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of Ascending, Multiple Oral Doses of SPD489 (Lisdexamfetamine Dimesylate) in Clinically Stable Adults with Schizophrenia (Shire SPD489-119)
Shire Pharmaceuticals Wayne, PA	A Phase 2, Multicenter, Double-blind, Parallel-group, Randomized, Placebo-controlled, Forced-dose Titration, Dose-ranging Efficacy and Safety Study of SPD489 in Combination with an Antidepressant in the Treatment of Adults with Major Depressive Disorder with Inadequate Response to Prospective Treatment with an Antidepressant (Shire SPD 489-209)
Zogenix Inc. Emeryville	A Long-Term Open-Label Safety Study of Hydrocodone Bitartrate Controlled-Release Capsules with Flexible Dosing to Treat Subjects with Moderate to Severe Pain. (Zogenix ZX002-0802)

APPENDIX C

CURRENTLY OPEN *(December 31, 2011)* RESEARCH STUDIES
ON THE TREATMENT OF CONTROLLED SUBSTANCE ABUSE

Investigator or Sponsor	Description or Title of Research Study
Keith E. Flower, M.D. APRL/CPMC Research Institute San Francisco, CA	A Pilot Trial of Naltrexone for Methamphetamine Addiction - Role of the A118G SNP
Gantt P. Galloway, Pharm.D. APRL/CPMC Research Institute San Francisco, CA	A Dose Ranging Study of Modafinil for Methamphetamine Dependence
Keith Heinzerling, MD, MPH UCLA ISAP Los Angeles, CA	Pharmacogenomics and Medication Development for Methamphetamine Dependence
Keith Heinzerling, MD, MPH UCLA ISAP Los Angeles, CA	Pilot Trial of Bupropion versus Placebo for Methamphetamine Abuse in Adolescents
Walter Ling, M.D. UCLA ISAP Los Angeles, CA	Sustained-Release Methylphenidate for management of Methamphetamine Dependence
Lara Ray, Ph.D. UCLA Los Angeles, CA	Pharmacogenetics of Naltrexone for Methamphetamine Use Disorder
Steven Shoptaw, Ph.D. UCLA. Los Angeles, CA	Phase I Safety Interaction Trial of Ibudilast with Methamphetamine

Investigator or Sponsor	Description or Title of Research Study
Steven Shoptaw, Ph.D. UCLA. Los Angeles, CA	Varenicline for Methamphetamine Dependence
NIDA Rockville, MD	Cocaine Use Reduction with Buprenorphine (CURB) (CTN-0048)
Titan Pharmaceuticals / CRO - PPD S. San Francisco, CA	A Randomized, Placebo and Active-Controlled, Multi-Center Study of Probuphine in Patients with Opioid Dependence (Titan PRO-806)

APPENDIX D

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

§ 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 § 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 § 11480 or § 11481. Complete records of receipts, stocks at hand, and use of these controlled substances shall be kept.

§ 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 § 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.

§ 11480. Cont.

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 § 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.

§ 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.

§ 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.

§ 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.

§ 24172. Experimental subject's bill of rights; contents

As used in the chapter, "experimental subject's bill of rights," means a list of the rights of a subject in a medical experiment, written in a language in which the subject is fluent. Except as otherwise provided in § 24175, this list shall include, but not be limited to the subject's right to:

(a) Be informed of the nature and purpose of the experiment.

(b) Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.

(c) Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.

(d) Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.

(e) Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.

(f) Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.

(g) Be given an opportunity to ask any questions concerning the experiment or the procedures involved.

(h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

§ 24172. Cont.

(i) Be given a copy of the signed and dated written consent form as provided for by § 24173 or § 24178.

(j) Be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.

§ 24173. Informed consent

As used in this chapter, "informed consent" means the authorization given pursuant to § 24175 to have a medical experiment performed after each of the following conditions have been satisfied:

(a) The subject or subject's conservator or guardian, or other representative, as specified in § 24175, is provided with a copy of the experimental subject's bill of rights, prior to consenting to participate in any medical experiment, containing all the information required by § 24172, and the copy is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in § 24175.

(b) A written consent form is signed and dated by the subject or the subject's conservator or guardian, or other representative, as specified in § 24175.

(c) The subject or subject's conservator or guardian, or other representative, as specified in § 24175, is informed both verbally and within the written consent form, in nontechnical terms and in a language in which the subject or the subject's conservator or guardian, or other representative, as specified in § 24175, is fluent, of the following facts of the proposed medical experiment, which might influence the decision to undergo the experiment, including, but not limited to:

(1) An explanation of the procedures to be followed in the medical experiment and any drug or device to be utilized, including the purposes of the procedures, drugs, or devices. If a placebo is to be administered or dispensed to a portion of the subjects involved in a medical experiment, all subjects of the experiment shall be informed of that fact; however, they need not be informed as to whether they will actually be administered or dispensed a placebo.

§ 24173. Cont.

(2) A description of any attendant discomfort and risks to the subject reasonably to be expected.

(3) An explanation of any benefits to the subject reasonably to be expected, if applicable.

(4) A disclosure of any appropriate alternative procedures, drugs, or devices that might be advantageous to the subject, and their relative risks and benefits.

(5) An estimate of the expected recovery time of the subject after the experiment.

(6) An offer to answer any inquiries concerning the experiment or the procedures involved.

(7) An instruction to the subject that he or she is free to withdraw his or her prior consent to the medical experiment and discontinue participation in the medical experiment at any time, without prejudice to the subject.

(8) The name, institutional affiliation, if any, and address of the person or persons actually performing and primarily responsible for the conduct of the experiment.

(9) The name of the sponsor or funding source, if any, or manufacturer if the experiment involves a drug or device, and the organization, if any, under whose general aegis the experiment is being conducted.

(10) The name, address, and phone number of an impartial third party, not associated with the experiment, to whom the subject may address complaints about the experiment.

(11) The material financial stake or interest, if any, that the investigator or research institution has in the outcome of the medical experiment. For purposes of this section, "material" means ten thousand dollars ($10,000) or more in securities or other assets valued at the date of disclosure, or in relevant cumulative salary or other income, regardless of when it is earned or expected to be earned.

§ 24173. Cont.

(d) The written consent form is signed and dated by any person other than the subject or the conservator or guardian, or other representative of the subject, as specified in § 24175, who can attest that the requirements for informed consent to the medical experiment have been satisfied.

(e) Consent is voluntary and freely given by the human subject or the conservator or guardian, or other representative, as specified by § 24175, without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence.