JOHN J. MURPHY, MD.
216 SE Osceola Street
Stuart, Fl 34994

EDUCATION:

1994-1996 Fellowship, Child and Adolescent Psychiatry
1996 Board Eligible Child and Adolescent Psychiatry
Los Angeles County + University of Southern California
Los Angeles, California

1992- 1994 Residency, Psychiatry
1994Board Eligible Psychiatry
Los Angeles County + University of Southern California
Los Angeles, California

1985- 1986 PGY1, PGY2, General Surgery
Orlando Regional Medical Center
Orlando, Florida

1984 MD University of Miami School Of Medicine
Miami, Florida

1980 B.A., Biology
Wabash College
Crawfordsville, Indiana

Academic Appointment:

Clinical Assistant Professor
University of Southern California School of Medicine Psychiatry and Behavioral Science Department
Los Angeles, California 1996 - 2016

Corporate Advisory Board Appointment:

Otsuka Pharmaceutical
Lundbeck
Novartis
Wyeth
Pfizer

LICENSURE:

California State Medical License, License No. G61442
Florida State Medical License, License No. ME90235

EXPERIENCE:

Present Private Practice Adult Psychiatry
Stuart, Fl
1/1/17 to present

Investigator
Southwestern Research Inc
Beverly Hills, Ca 90210
Nov 1994 - June 2016

California Advanced Neurotherapeutics
Los Angeles, CA
Sep 2016 - Jan 1, 2017

Investigator
Pacific Institute of Medical Research
Los Angeles, CA
May 2016 - Jan 1, 2017

Medical Director
Southwestern Research, Inc.
Beverly Hills, California
Nov 1994 – May 2016

Private Practitioner
Child/Adolescent and General Psychiatry
Beverly Hills, California
1994 – 2017

Medical Director
House Med, Inc.
Orlando, Florida
1989 – 1992

Private Practitioner
General Medicine
Orlando, Florida
1987 – 1992

Board of Directors
Medical Director
Give Kids the World
1990-1992

Exclusive Provider
Private Health Care
Walt Disney World
Orlando, Florida
1987 – 1992

EXPERIENCE (continued):

Research Associate
Orlando Laser Research Center
Microsurgery Division
Orlando, Florida
1986 – 1987

Membership

- Member, American Medical Association
- Diplomate, National Board of Medical Examiners
- Member, American Psychiatric Association
- Member, American Academy of Sleep Medicine
- Florida Medical Association

US Patents

Inventor of these Patents
Methods and compositions for alleviating stuttering

6,855,721
7,858,638
8,242,132
8,618,127

US TradeMarks

Owner of these Trade Marks
87628246
87812132
87628852

CLINICAL TRIAL EXPERIENCE:

Major Depression Disorder

1998	Solvay Pharmaceuticals	A Multi-center, Double-Blind, Randomized Parallel Group Study of the Efficacy, Safety, Tolerability of a Flexible Dose Regimen of Fesinoxan Versus Placebo in Outpatients with Major Depressive Disorder with Fluoxetine as an Active Control
1998	Pfizer Inc., Central Research Division	A Six-Week, Double-Blind, Placebo and Fluoxetine Controlled Multi center Study to Evaluate the Safety and Efficacy of Oral CP-122-721 in Outpatients with Major Depressive Disorder
1998	Synthelabo Research, Inc.	Comparison of the Efficacy and Safety of Befloxatone 2.5 mg OD Versus Placebo in Outpatients with Moderate to Severe Major Depressive Disorder; A Randomized, Double-Blind, 8-Week Multi-Center Phase II Trial Protocol No. 2918
1998	Organon, Inc.	A Multi center, Randomized, Double-Blind, Placebo-Controlled, Efficacy and Safety Study of Remeron in Outpatient Children and Adolescents with Major Depressive Disorder Protocol No. 003-045
1998-1999	Merck Research	A Double-Blind, Randomized, Multi center, Parallel Design Study to Evaluate the Efficacy and Safety of Individual Maximum Tolerated Doses of EMD 68 843 in Comparison with Placebo and Fluoxetine in Outpatients with Major Depressive Disorder
1999	Bristol-Myers Squibb	A Multi center, Double-Blind, Placebo and Sertraline Controlled, Randomized Parallel Group, Flexible Dose Trial of Nefazodone ER in the Treatment of Depressed Patients
1999	Bristol-Myers Squibb	A Multi center, Double-Blind, Flexible Dose Safety Trial Comparing Nefazedoene ER to Nefazedoene IR in the Treatment of Depressed Patients
1999	Pharmacia & Upjohn	Open-Label Reboxetine Continuation Therapy
1999	Pharmacia & Upjohn	Open-Label Reboxetine Rescue and Continuation Therapy
1999	Sanofi-Synthelabo Research	A Double-Blind Placebo and Paroxetine Controlled, Multi center Study Evaluating the Efficacy and Safety of SR142801 in Patients with Major Depressive Disorder
1999-2001	Eli Lilly & Co.	The Combination of Olanzapine and Fluoxetine in Treatment Resistant Depression Without Psychotic Features

CLINICAL TRIAL EXPERIENCE (continued):

Depression (continued):

1999-2001	Merck & Co.	A Double-Blind, Multi center, Placebo-Controlled Study of L-759274 in the Treatment of Outpatients with Major Depression Melancholic Features
2000-2001	Pharmacia & Upjohn	Reboxetine Versus Placebo in the Treatment of Major Depressive Disorder Resistant to Fluoxetine
2000-2001	Pharmacia & Upjohn	Pharmacogenomics Blood Sampling Protocol
2000-2002	Wyeth-Ayerst Research	A Double-Blind, Placebo-Controlled Comparative Efficacy Study of Venlafaxine ER and Sertraline in Producing Remission in Outpatients with Major Depressive Disorder
2001	Pharmacia & Upjohn	Reboxetine, Placebo and Paroxetine Comparison in Patients with Depressive Disorder
2001	Organon, Inc.	A Single Dose, Pharmacokinetic Trial of Remeron in Children and Adolescents with Major Depression
2001	GlaxoSmithKline Beecham	A Double-Blind, Placebo Controlled, Fixed Dosage Study Comparing the Efficacy and Tolerability of Paroxetine CR and Citalopram to Placebo in the Treatment of Major Depressive Disorder with Anxiety
2001	Organon, Inc.	Open-Label, Multiple Oral Dose Study to Assess the Steady State Pharmacokinetics of Org 33062 ER in Children and Adolescents with Major Depressive Disorder
2001-2002	Organon, Inc.	A Double-Blind, Multi-Center, Randomized, Placebo-Controlled, Efficacy and Safety Study of ORG 33062 ER and Fluoxetine in Subjects who Suffer from Major Depressive Disorder with Atypical Features
2001-2002	Organon, Inc.	A Double-Blind, Multi-Center Extension Trial in Subjects Who Suffer from Major Depressive Disorder with Atypical Features who Participated in the Placebo and Fluoxetine Controlled Study of Org 33062 ER
2001-2002	Organon, Inc.	A Double-Blind, Randomized, Placebo and Paroxetine Controlled, Multi center, Dose-Finding Trial with ORG 34517 in Outpatients with Moderate to Severe Major Depressive Disorder

CLINICAL TRIAL EXPERIENCE (continued):

Depression (continued):

2001-2002	Sanofi-Synthelabo Research	A Double-Blind, Placebo and Paroxetine Controlled Multi center, Dose-Ranging Study Evaluating the Efficacy and Safety of SR48968C in Outpatients with Major Depressive Disorder
2001-2002	Wyeth-Ayerst Research	Double-Blind, Placebo-Controlled Study of Venlafaxine ER in Children and Adolescents with Major Depressive Disorder
2001-2002	Wyeth-Ayerst Research	A Double-Blind, Placebo-Controlled Comparative Efficacy Study of Venlafaxine ER and Sertraline in Producing Remission in Outpatients with Major Depressive Disorder
2001-2002	GlaxoSmithKline	A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study Evaluating Efficacy and Safety of SB-29060 Controlled Release (12.5 and 25 mg/day) Versus Placebo in Patients with Major Depressive Disorder
2001-2002	Pfizer, Inc.	A Phase IIB, Seven-Week, Double-Blind, Placebo and Paroxetine Controlled Multi center Study to Evaluate the Safety and Efficacy of Oral CP-122, 721 in Outpatients with Major Depressive Disorder and Associated Somatic Symptoms
2001-2002	Pfizer, Inc.	A Seven-Week, Double Blind, Extension of Protocol: A Phase IIB, Seven-Week, Double-Blind, Placebo and Paroxetine-Controlled Multi center Study to Evaluate the Safety and Efficacy of Oral CP-122, 721 in Outpatients with Major Depressive Disorder and Associated Somatic Symptoms
2001-2002	Pfizer, Inc.	An Eight-Week, Double-Blind, Placebo-Controlled Multi center Study to Evaluate the Safety and Efficacy of 2 Doses of CP-448, 187 (1.5 and 3 mg) and Y in Subjects with Major Depressive Disorder
2001-2002	Forest Laboratories	Double-Blind, Comparison of the Safety and Efficacy of Escitalopram and Fluoxetine in the Treatment of Fluoxetine Non-responders
2001-2002	Forest Laboratories	Two-Week Double-Blind Placebo-Controlled Study of Escitalopram in the Treatment of Severe Major Depression. Phase A: Double-Blind Comparison of the Safety and Efficacy of Escitalopram and Placebo After Two Weeks of Treatment of Patients with Severe Major Depression. Phase B: Double-Blind Comparison of the Safety and Efficacy of Escitalopram and Placebo After Eight Weeks of Treatment of Patients with Severe Major Depression

CLINICAL TRIAL EXPERIENCE (continued):

Depression (continued):

2001-2002	Forest Laboratories	An Open-Label Extension Study of the Safety and Efficacy of Escitalopram in Patients with Major Depressive Disorder
2002	Eli Lilly & Co.	The Study of Olanzapine and Fluoxetine in Combination for Treatment Resistant Depression Without Psychotic Features
2002	Eli Lilly & Co.	The Study of Olanzapine and Fluoxetine in Combination for Treatment Resistant Depression Without Psychotic Features
2002	Wyeth	Multi center, Randomized, Double-Blind, Placebo-Controlled Study of Two Fixed Doses of Des-Venlafaxine Succinate in Adult Outpatients with Major Depression
2002	GlaxoSmithKline	A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Flexible-Dose Study Evaluating Efficacy and Safety of SB-659746-A in Patients with Major Depressive Disorder
2002	Eli Lilly & Co.	LY544344 Versus Placebo in Patients with Mixed Anxiety-Depressive Disorder in a Primary Care Setting
2002-2003	GlaxoSmithKline	An 8-Week, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Multi center, Fixed Dose Study Comparing the Efficacy and Safety of GW597599B or Paroxetine to Placebo in Moderately to Severely Depressed Patients with Major Depressive Disorder
2003	Forest Laboratories	A Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of Escitalopram in Pediatric Depression
2003	Merck & Co.	A Double-Blind, Multi center, Placebo-Controlled Study of MK-0869 in the Treatment of Patients with Major Depressive Disorder
2003	Eli Lilly & Co.	Duloxetine Versus Venlafaxine Extended Release in the Treatment of Major Depressive Disorder
2003	Merck & Co.	A Double-Blind, Multi center, Placebo and Active-Controlled Acute and Extension Study of MK-0869 in the Treatment of Patients with Major Depressive Disorder with Melancholic Features
2003	Merck & Co.	A Worldwide, Multi center, Double-Blind, Parallel, Active-Controlled, Long-Term Safety Study of MK-0869 in Outpatients with Major Depressive Disorder

CLINICAL TRIAL EXPERIENCE (continued):

Depression (continued):

2003	Fabre-Kramer	A Double-Blind, Multi center, Randomized, Placebo-Controlled Efficacy and Safety Study of Org 33062 ER in Subjects with Major Depressive Disorder
2003	Sanofi-Synthelabo	A Double-Blind, Multi center Study Evaluating the Efficacy and Safety of One Fixed Dose of SR58611A (700 mg/day) Versus Placebo and Paroxetine (20 mg/day) in Patients with a Recurrent Major Depressive Episode
2003	Johnson & Johnson	A 6-Week, Randomized, Double-Blind, Parallel-Group, Active and Placebo-Controlled Trial to Assess the Efficacy of R228060 in Adult Subjects with Major Depressive Disorder (MDD)
2003	Eli Lilly & Co.	Validation of Daily Telephone Self-Assessment in the Study of Antidepressant Treatment Outcome
2003	GlaxoSmithKline	A Multi center, Double-Blind,Placebo-Controlled Comparison of the Efficacy and Safety of Extended-Release Bupropion Hydrochloride 300 mg/day and Placebo Administered for Eight Weeks for the Treatment of Adult Outpatients with Major Depressive Disorder and Symptoms of Decreased Energy, Pleasure, and Interest
2003-2004	Wyeth	A Multi center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of DVS-233 SR for Prevention of Depressive Relapse in Adult Outpatients with Major Depressive Disorder
2003-2004	GlaxoSmithKline	A Multi center, Double-Blind, Randomized, Placebo-Controlled Comparison of the Effects on Sexual Functioning of Extended-Release Buproprion Hydrochloride (300-450mg) and Escitalopram (10-20mg) in Outpatients with Moderate to Severe Major Depression Over an Eight-Week Treatment Period
2003-2005	Wyeth	A 10-Month Open-Label Evaluation of the Long-Term Safety of DVS-233 SR in Outpatients with Major Depressive Disorder
2003-2005	Wyeth	A Multi center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Three Fixed Doses (50 mg, 100 mg, or 200 mg) of DVS-233 SR in Adult Outpatients with Major Depressive Disorder

CLINICAL TRIAL EXPERIENCE (continued):

Depression (continued):

2004-2005	GlaxoSmithKline	A Twelve-Week, Multi-Center, Randomized, Double-blind, Double-Dummy, Parallel-Group, Active Controlled, Escalating Dose Study to Compare the Effects on Sexual Functioning of Wellbutrin XL Extended-release (150-450 mg/day) and Extended-release Effexor XR (75-225 mg/day) in Subjects with Major Depressive Disorder
2004-2005	Wyeth	A Multi center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Efficacy and Safety Study of a Flexible Dose of DVS-233 in Adult Outpatients with Major Depressive Disorder
2004-2006	GlaxoSmithKline	A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Fixed-Dose Study Evaluating the Efficacy and Safety of GW679769 in Subjects with Major Depressive Disorder
2005-2006	Bristol-Myers Squibb	A Multi center, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Aripiprazole as Adjunctive Therapy in the Treatment of Patients with Major Depressive Disorder
2005-2006	Sanofi-Aventis	An Eight Week, Double-Blind, Placebo Controlled, Multi center Study with Escitalopram (10 mg qd) as Positive Control, Evaluating the Efficacy, Safety, Tolerability of a Fixed Dose of SR58611A (350 mg q12) in Outpatients with Major Depressive Disorder
2005-2006	Sanofi-Aventis	An Eight Week, Double-Blind, Placebo Controlled, Multi center Study with Escitalopram (10mg qd) as Positive Control, Evaluating the Efficacy, Safety, Tolerability of a Fixed Dose of SR58611 (350mg q12) in Outpatients with Major Depressive Disorder (MDD)
2005-2007	Bristol-Myers Squibb	A Multi center, Long-Term, Open-Label Study to Assess the Safety and Tolerability of Aripiprazole as Adjunctive Therapy in the Treatment of Outpatients with Major Depressive Disorder
2005-2007	Sanofi-Aventis	An Eight-Week, Multi center, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy, Safety and Tolerability of One Fixed 100 mg Dose of Saredutant in Patients with Major Depressive Disorder

CLINICAL TRIAL EXPERIENCE (continued):

Depression (continued):

2006-2007	Wyeth	A Multi center, Randomized, Double-Blind, Placebo-Controlled, Duloxetine-Referenced, Parallel-Group Study to Evaluate the Efficacy and Safety of 2 Fixed Doses (50mg, 100mg) of Desvenlafaxine Sustained-Release Tablets in Adult Outpatients with Major Depressive Disorder
2006-2007	AstraZeneca	A Multi center, Double-blind, Randomized, Parallel-group, Placebo-controlled and Active-controlled Phase III Study of the Efficacy and Safety of Quetiapine Fumarate Sustained-release (Seroquel) as Mono therapy in the Treatment of Patients with Major Depressive Disorder (Diamond Study)
2006-2008	Sanofi-Aventis	A multi center, randomized, 24-52 week, double-blind, placebo-controlled study to evaluate the efficacy, safety and tolerability of Saredutant 100 mg once daily in the prevention of relapse of depressive symptoms in outpatients with major depressive disorder who achieved an initial response to 12 weeks of open-label treatment with Saredutant 100 mg once daily
2007-2008	Eli Lilly & Co.	Duloxetine Versus Placebo in Patients with Major Depressive Disorder (MDD): Assessment of Energy and Vitality in MDD
2007-2008	Labopharm	A Randomized, Double-blind, Two-arm Study Comparing the Efficacy and Safety of Trazodone Contramid® OAD and Placebo in the Treatment of Unipolar Major Depressive Disorder
2007-2008	Sanofi-Aventis	An eight-week, double-blind, placebo-controlled study to evaluate the efficacy, safety, and tolerability of Saredutant 100 mg once daily in combination with Escitalopram 10 mg once daily in patients with major depressive disorder
2007-2009	Novartis Pharmaceuticals	A 52-week, randomized, double-blind, placebo-controlled, multi-center, parallel-group study of the long-term efficacy, tolerability and safety of Agomelatine 25 and 50 mg in the prevention of relapse of Major Depressive Disorder (MDD) following open-label treatment of 16-24 weeks
2007-2009	Sepracor	A Double-Blind, Randomized, Placebo-Controlled Study Examining, the Safety, Efficacy, and Tolerability of SEP-2252891 in Subjects with Major Depressive Disorder (including Atypical and Melancholic Features)

CLINICAL TRIAL EXPERIENCE (continued):

Depression (continued):

2008	Johnson & Johnson	A Phase IIa Multi center, Randomized, Double-Blind, Double-Dummy, and Placebo- and Active-Controlled Study to Investigate the Safety and Efficacy of JNJ-18038683 Administered to Subjects with Major Depressive Disorder
2008	Pfizer, Inc.	An Eight-Week, Double-Blind, Group-Sequential Design, Placebo Controlled Trial to Evaluate the Safety and Efficacy of the Co-Administration of Sertraline and Elzasonan (CP-448,187) in Outpatient with Major Depressive Disorder
2008-2009	CeNeRx	A Randomized, Double-Blind, Placebo-Controlled Parallel-Group, Assessment of the Efficacy, Safety and Tolerability of CX157 60mg TID in Subjects with Major Depressive Disorder
2008-2009	GlaxoSmithKline	A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Fixed Dose Study Evaluating the Efficacy and Safety of GW679769 in Subjects with Major Depressive Disorder
2009	Takeda	A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Active-Referenced, Fixed-Dose Study Comparing the Efficacy and Safety of 2 Doses of Vortioxetine in Acute Treatment of Adults With Major Depressive Disorder
2009	Eli Lilly & Co.	A Randomized, Double-Blind Comparison of LY2216684 and Placebo and Long Term Treatment with LY2216684 in Adult Patients with Major Depressive Disorder
2009	Wyeth	A Multi center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of 2 Fixed Doses (25 and 50 MG/Day) of Desvenlafaxine Succinate Sustained-Release Tablets in Adult Outpatients with Major Depressive Disorder
2009-2010	Takeda	Long-Term, Open-Label, Flexible-Dose, Extension Study Evaluating the Safety and Tolerability of Vortioxetine in Subjects With Major Depressive Disorder
2009-2010	Wyeth	A Multi center, Double-Blind, Placebo-Controlled, Randomized, Withdrawal, Parallel Group Study to Evaluate the Efficacy and Safety of 50 mg/day of Desvenlafaxine Succinate Sustained-Release (DVS SR) in Adult Outpatients with Major Depressive Disorder
2010-2011	Cephalon	A Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dosage Study to Evaluate the Efficacy and Safety of Armodafinil Treatment (150 and 200 mg/Day) as Adjunctive Therapy in Adults With Major Depression Associated With Bipolar I Disorder

CLINICAL TRIAL EXPERIENCE (continued):

Depression (continued):

2009-2010	Pfizer, Inc.	A Multi center, Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Tolerability of Indiplon Therapy Initiated with Sertraline Versus Sertraline Mono therapy in Subjects with Insomnia and Co-Existing Major Depressive Disorder
2009-2010	Otsuka	A Phase 2, Multi center, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of OPC-34712 (1 to 3 mg/Day) (brexpiprazole) an Adjunctive Therapy in the Treatment of Patients with Major Depressive Disorder
2009-2010	Eli Lilly & Co.	A Phase 4, 8 Week, Double-Blind, Randomized, Placebo-Controlled Study Evaluating the Efficacy of Duloxetine 60mg once Daily in Outpatients with Major Depressive Disorder and Associated Painful Physical Symptoms
2009-2011	Forest Laboratories	A Double-blind, Placebo-Controlled, Fixed-Dose Study of Vilazodone in Patients with Major Depressive Disorder
2010-2011	Otsuka	A Phase 2, Multi center, Open-label Study to Assess the Safety and Tolerability of Oral OPC-34712 (brexpiprazole) as Adjunctive Therapy in Adult Patients with Major Depressive Disorder
2010-2011	Forest Laboratories	A Long-Term, Open-label Extension Study of Vilazodone in Adult Patients With Major Depressive Disorder
2010-2011	Forest Laboratories	A multi-center, Randomized, Double-blind, Placebo-Controlled, Relapse-prevention Study with F2695 SR in Patients with Major Depressive Disorder
2010-2011	Pfizer, Inc.	A multi-center, Randomized, Double-blind, Placebo-Controlled, Relapse-prevention Study with F2695 SR in Patients with Major Depressive Disorder
2010-2011	Pfizer, Inc.	A Multi center, Parallel Group, Randomized, 10-Week, Double-blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of 50 mg of desvenlafaxine succinate sustained-release formulation (DVS SR) in the Treatment of Peri- and Postmenopausal Women with Major Depressive Disorder
2010-2011	Otsuka	A Phase 2, Multi center, Randomized, Double-blind, Placebo Controlled Study of the Safety and Efficacy of OPC-34712 (brexpiprazole) as Adjunctive Therapy in the Treatment of Adults with Major Depressive Disorder
2011	Pfizer	A 10 Month Open-Label Evaluation Of The Long-Term Safety Of DVS-233 SR (Desvenlafaxine Succinate) In Outpatients With Major Depressive Disorder.

CLINICAL TRIAL EXPERIENCE:

Depression Disorder

2010-2011	Novartis Pharmaceuticals	An 8-week, Randomized, Double-blind, Placebo Controlled, Parallel-group, Multi-center Study of the Efficacy and Safety of Agomelatine 0.5 mg and 1 mg Sublingual Tablets Administered Once Daily in Patients with Major Depressive Disorder (MDD)
2010-2011	Novartis Pharmaceuticals	A 52-week, Multi-center, Open Label Study of the Safety and Tolerability of Agomelatine Sublingual Tablets in Patients with Major Depressive Disorder
2010-2011	Takeda	A Phase 3, Long-term, Open-label-, Flexible-dose, Extension Study Evaluating the Safety and Tolerability of Lu AA21004 (Vortioxetine) (15 and 20 mg) in Subjects with Major Depressive Disorder
2010-2011	Takeda	A Phase 3, Randomized, Double-blind, Placebo-Controlled, Duloxetine-referenced, Fixed Dose Study Comparing the Efficacy and Safety of 2 doses (15 and 20 mg) of Lu AA21004 (Vortioxetine) in Subjects with Major Depressive Disorder
2010-2011	AstraZeneca	A Multi-center, Randomized, Double-blind, Parallel Group, Placebo-Controlled, Phase III, Long-term Safety and Tolerability Study of TC-5214 (S-mecamylamine) as an Adjunct to an Antidepressant in Patients with Major Depressive Disorder who Exhibit an Inadequate Response to Antidepressant Therapy
2010-2011	AstraZeneca	A Multi-center, Randomized, Double-blind, Parallel Group, Placebo-Controlled, Phase III, Efficacy and Safety Study of 3 Fixed Dose Groups of TC-5214 (S-mecamylamine) as an Adjunct to an Antidepressant in Patients with Major Depressive Disorder who Exhibit an Inadequate Response to Antidepressant Therapy
2011	AstraZeneca	A Phase IIb, Randomized, Double-Blind, Placebo-Controlled, Active Controlled, Parallel Group, Multi center Study to Assess the Safety and Efficacy of 2 Fixed Dose Groups of TC-5214 (S-mecamylamine) as Mono-therapy Treatment in Patients with Major Depressive Disorder with an Inadequate Response to Antidepressant Therapy
2011 - 2012	Pfizer	A Phase IV, Multi center, Randomized, 8-Week, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy of 2 Fixed Doses (50 and 100 mg/day) of Desvenlafaxine Sustained-Release Tablets in Adult Outpatients with Major Depressive Disorder
2012 – 2013	Forest	A Phase 3 Double-Blind, Placebo-Controlled, Fixed-Dose Study of Levomilnacipran SR in Patients with Major Depressive Disorder

CLINICAL TRIAL EXPERIENCE (continued):

Depression (continued):

2012 - 2013	Otsuka	A Phase 3, Multi center, Randomized, Double-blind, Placebo- and Active Comparator-controlled Trial of Flexible-dose OPC-34712 (Brexpiprazole/Rexulti) as Adjunctive Therapy in the Treatment of Adults with Major Depressive Disorder
2012 - 2013	Otsuka	A Long-term, Phase 3, Multi center, Open-label Trial to Evaluate the Safety and Tolerability of Oral Aripiprazole (Abilify) as Adjunctive Therapy in Adults with Major Depressive Disorder
2012 - 2013	Otsuka	A Phase 3, Multi center, Randomized, Double-Blind, Placebo-Controlled Trial of the Safety and Efficacy of Fixed-dose Brexpiprazole/Rexulti as Adjunctive Therapy in the Treatment of Adults with Major Depressive Disorder
2012 - 2013	Forest	A Multi center, Randomized, Double-Blind, Placebo-Controlled, Relapse Prevention Study with Vilazodone in Patients with Major Depressive Disorder
2015	Alkermes, Inc	A Phase 3 Efficacy and Safety Study of ALKS 5461 for the Adjunctive Treatment of Major Depressive Disorder (the FORWARD-3 Study)
2016	Lundbeck-Takeda	A Randomized, Double-Blind, Placebo-Controlled, Relapse Prevention Study Evaluating the Efficacy and Safety of Vortioxetine (5, 10 and 20 mg) in Adults With Major Depressive Disorder, Phase IV
2016	Allergan	A Double-blind, Placebo-controlled Study of Rapastinel (GLYX-13) as Adjunctive Therapy In Major Depressive Disorder RAP-MD-02

Bipolar Disorder

2001-2002	AstraZeneca	A Multi center, Double-blind, Randomized, Placebo-controlled, Double-Dummy, Trial of the Use of Quetiapine in the Treatment of Patients with Bipolar Depression
2003-2004	Eli Lilly & Co.	Olanzapine/Fluoxetine Combination Versus Lamictal in the Treatment of Bipolar I Depression

2003-2005	GlaxoSmithKline	A Multi center, Double-Blind, Placebo-Controlled, Fixed-Dose, 8-Week Evaluation of the Efficacy and Safety of Lamotrigine in the Treatment of Bipolar Disorder Patients Currently Experiencing a Major Depressive Episode
2003-2005	GlaxoSmithKline	A Multi center, Double-Blind, Placebo-Controlled, Fixed-Dose, 8-Week Evaluation of the Efficacy and Safety of Lamotrigine in the Treatment of Bipolar Disorder Patients Currently Experiencing a Major Depressive Episode

CLINICAL TRIAL EXPERIENCE (continued):

Bipolar Disorder (continued):

2003-2005	Lunbeck	Randomised, Double-blind, Parallel-Group, Placebo-Controlled, Quetiapine-Referenced, Fixed Dose Study of X in the Treatment of Depression in Patients with Bipolar I or II
2005-2006	Wyeth	A Multi center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of Bifeprunox in the Treatment of Depression in Outpatients with Bipolar Disorder
2005-2006	Wyeth	An Extension Study to Evaluate the Long-Term Safety and Tolerability of Bifeprunox in the Treatment of Outpatients with Bipolar Disorder
2007	AstraZeneca	A Multi center, Randomized, Parallel-group, Double-blind, Phase III Comparison of the Efficacy and Safety of X (oral tablets 400 mg to 800 mg daily in divided doses) to Placebo When Used as Adjunct to Mood Stabilizers (Lithium or Valproate) in the Maintenance Treatment of Bipolar I Disorder in Adult Patients
2012 – 2013	Forest	A Phase 2 Double-Blind, Placebo-Controlled Evaluation of the Safety and Efficacy of cariprazine in Patients with Bipolar Depression.
2013	Otsuka	A 52-Week, Multi center, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy, Safety, and Tolerability of an Intramuscular Depot Formulation of X as Maintenance Treatment in Patients with Bipolar I Disorder

Generalized Anxiety Disorder

Year	**Sponsor**	
1995-1996	Wyeth-Ayerst Research	Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Finding Study of Venlafaxine ER in Outpatients with Generalized Anxiety Disorder Protocol No. 0600B2-210-US
1996-1997	Wyeth-Ayerst Research	Six-Month Double-Blind, Placebo-Controlled, Parallel-Group Comparison of X and Placebo in Outpatients with Generalized Anxiety Disorder
1997-1998	Bristol-Myers Squibb	A Double-Blind, Randomized Trial of Three Fixed Doses of X Compared to Placebo in the Treatment of Anxious Outpatients

CLINICAL TRIAL EXPERIENCE (continued):

Anxiety Disorder

1998	SmithKline Beecham Pharmaceuticals	A Randomized, Double-Blind, Placebo-Controlled, Flexible Dosage Trial to Evaluate the Efficacy and Tolerability of X in Patients with Generalized Anxiety Disorder
1998-1999	Bristol-Myers Squibb	A Double-Blind, Randomized, Flexible Dose Trial of X or Y Compared to Placebo in the Treatment of Anxious Outpatients
1999	Bristol-Myers Squibb	A Multi-Center, Randomized, Double-Blind, Parallel Group, Placebo-Controlled Study Evaluating the Efficacy and Safety to Two Fixed Dose Ranges of X (15-30mg and 45-60 mg) in Children and Adolescents (Aged 6-17) with Generalized Anxiety Disorders
2001-2002	Merck Research	A Double-Blind, Multi center, Acute Study of Two Doses of X Versus Y and Placebo in the Treatment of Outpatients with Generalized Anxiety Disorder
2001-2002	Wyeth	Double-Blind, Placebo-Controlled Study of X ER in Children and Adolescents with Generalized Anxiety Disorder
2001-2002	Pfizer, Inc.	A Randomized, Double-Blind, Alprazolam and Placebo-Controlled Study of the Efficacy and Safety of X in Outpatients with Generalized Anxiety Disorder
2001-2002	Forest Laboratories	Flexible Dose Comparison of the Safety and Efficacy of X and Placebo in the Treatment of Generalized Anxiety Disorder
2001-2002	Forest Laboratories	An Open-Label Extension Study of the Safety and Efficacy of X in Patients with Generalized Anxiety Disorder
2001-2002	GlaxoSmithKline	A Randomized, Double-Blind, Placebo-Controlled, Flexible Dosage Trial to Evaluate the Efficacy and Tolerability of X CR in Patients with Generalized Anxiety Disorder (GAD)
2001-2003	Sanofi-Synthelabo Research	A Four-Week, Double-Blind, Placebo and Active Controlled, Dose-Ranging Study of X 3 Doses (5,15,50 mg per day) and Lorazepam (3 mg/day) in Out-Patients with Generalized Anxiety Disorder
2002	Biovail Corporation	A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dose Study of the Efficacy, Safety, and Tolerability of 60 mg X Extended Release Compared to Placebo in Patients with Generalized Anxiety Disorder Who Have Stable Disease Characteristics

CLINICAL TRIAL EXPERIENCE (continued):

Anxiety Disorder (continued):

2003	Cephalon, Inc.	A 12-Month, Open-Label, Flexible-Dosage Study to Evaluate the Safety of X at Dosages up to 16mg/day in Adults with Generalized Anxiety Disorder
2003-2004	Pharmacia Corporation	X 30 mg and 60 mg Once Daily Versus Placebo in Generalized Anxiety Disorder. A Randomized Double-Blind Placebo and Buspirone–Controlled Fixed-Dose Parallel-Group Multi center Study of 10 Weeks (Including a 2-Week Single-Blind Placebo Period)
2003-2005	Pharmacia Corporation	X 60 mg (or 30 mg) Once Daily in the Treatment of Generalized Anxiety Disorder. An Open Multi center Safety Study of 5 months, Including a 1 month drug-free follow-up period. Follow-up to studies I and II.
2004	Cephalon, Inc.	A 10-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Flexible-Dosage Study to Evaluate the Efficacy and Safety of X (up to 16 mg/day) in Treatment of Adults with Generalized Anxiety Disorder
2004-2006	Cephalon, Inc.	A 12-Month, Open-Label, Flexible-Dosage Study to Evaluate the Safety and Efficacy of X Treatment (up to 16 mg/day) in Adults with Generalized Anxiety Disorder
2005-2006	Eli Lilly & Co.	X Once Daily Compared with Placebo in the Treatment of Generalized Anxiety Disorder
2005-2006	Jazz Pharmaceuticals	A Randomized, Double-Blind, Placebo and Active Comparator Controlled, Parallel-Group Safety and Efficacy Study of X in Adults with Generalized Anxiety Disorder (GAD)
2005-2006	Novartis Pharmaceuticals	A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of the Efficacy, Safety and Tolerability of X in Patients with Generalized Anxiety Disorder
2005-2006	AstraZeneca	A Multi center, Randomized, Double-blind, Parallel-group, Placebo-controlled Study of the Efficacy and Safety of X Extended-Release Compared with Placebo as an Adjunct to Treatment in Patients with Generalized Anxiety Disorder who Demonstrate Partial or No Response to a Selective Serotonin Reuptake Inhibitor or Serotonin-Norepinephrine Reuptake Inhibitor Alone or in Combination with a Benzodiazepine

CLINICAL TRIAL EXPERIENCE (continued):

Anxiety Disorder (continued):

2005-2007	Jazz Pharmaceuticals	A Long-Term, Open-Label, Safety and Efficacy Study of X in Adults with Generalized Anxiety Disorder (GAD)
2006-2007	Pfizer, Inc.	A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, 5-Week Trial to Assess the Efficacy and Safety of X Compared to Placebo and Alprazolam Extended-Release in Patients with Generalized Anxiety Disorder
2006-2007	Predix Pharmaceuticals Holdings, Inc.	A Multi center, Open-label Study to Assess the Tolerability and Efficacy of X in Patients with Generalized Anxiety Disorder
2006-2007	AstraZeneca	A Multi center, Randomized, Double-blind, Parallel-group, Placebo-controlled, Active-controlled Study of the Efficacy and Safety of Sustained-release Compared with Placebo in the Treatment of Generalized Anxiety Disorder (Gold Study)
2006-2007	Pfizer, Inc.	A Phase 3, Randomized, Double-Blind, Placebo Controlled, Parallel Group, 10-Week Study Evaluating the Efficacy and Safety of X for the Treatment of Generalized Anxiety Disorder
2007	Sanofi-Aventis	An Eight-Week, Randomized, Double-blind, Placebo-controlled Study, with Escitalopram as an Active Control, to Evaluate the Efficacy, Safety and Tolerability of a X 100 mg Dose Once Daily, in Patients with Generalized Anxiety Disorder
2007-2008	AstraZeneca	A Multi-Center, Randomized, Placebo-Controlled, Double-Blind, Parallel Group, Efficacy and Safety Study of X in the Treatment of Generalized Anxiety Disorder (GAD)
2008-2009	Sepracor	A Double-Blind, Randomized, Placebo Controlled, Multi-Center Study Examining the Efficacy and Safety of X in Subjects with Generalized Anxiety Disorder
2008-2009	Pfizer, Inc.	A Phase 3, Randomized, Double-Blind, Parallel Group, 10-Week, Placebo Controlled Fixed Dose Study of X and Paroxetine Evaluating the Efficacy and Safety of X for the Treatment of Generalized Anxiety Disorder

2008-2009	Pfizer, Inc.	An 8-Week, Double-Blind, Placebo-Controlled, Phase 3 Trial of X (150-600 MG/Day) in the Adjunctive Treatment of Patients with Generalized Anxiety Disorder (GAD) Who Have Not Optimally Responded to Existing Therapies

CLINICAL TRIAL EXPERIENCE (continued):

Anxiety Disorder (continued):

2009	Synosia	A Multi-center Randomized, Double-Blind, Placebo-Controlled, Phase 2, Exploratory Study to Evaluate the Effect of X on Anxiety in Patients with Moderate to Severe Generalized Anxiety Disorder
2010	Takeda	A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Active-Referenced, Fixed-Dose Study Comparing the Efficacy and Safety of 3 Doses of X in Acute Treatment of Adults with Generalized Anxiety Disorder
2012 – 2013	Forest	A Double-Blind, Placebo-Controlled, Flexible-Dose Study of X in Patients with Generalized Anxiety Disorder.
2013	Forest	A Double-Blind, Placebo-Controlled, Flexible-Dose Study of X in Patients with Generalized Anxiety Disorder.

Sexual Dysfunction

2001-2003	Pfizer, Inc.	A Double-Blind, Placebo-Controlled, Parallel Group Design Dose-Ranging Study of Three Doses of X Vs. Placebo for the Treatment of Sexual Dysfunction (Arousal Disorder) in Postmenopausal Women
2001-2003	Pfizer, Inc.	A Double-Blind, Placebo-Controlled, Parallel Group Design Dose Ranging Study of Three Doses of X Vs. Placebo for the Treatment of Sexual Dysfunction (Hypoactive Desire) in Postmenopausal Women
2002-2003	Pfizer, Inc.	A Randomized, Double-Blind, Placebo-Controlled, Fixed Dose, Multi-Center Study to Evaluate the Efficacy, Safety and Toleration of Oral X Administered for 12 Weeks to Post-Menopausal Women Who Have Been Diagnosed with Female Sexual Arousal

2002-2003	Pfizer, Inc.	A Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Fixed Dose, Multi-Center Study to Evaluate the Efficacy, Safety and Toleration of Oral X Administered for 12 Weeks to Premenopausal Women Who Have Been Diagnosed with Female Sexual Disorder
2003	Pfizer, Inc.	An Open-Label, Multi-Center Extension Study to Evaluate the Safety, Toleration and the Sustained Efficacy of Oral X Administered to Women Who Have Been Diagnosed With Female Arousal Disorder

CLINICAL TRIAL EXPERIENCE (continued):

Stuttering

2009-2010	InterNeuron	A 3-arm, double-blind, placebo-controlled clinical trial to assess the efficacy, safety and tolerability of X for the treatment of adults with stuttering

Post-Traumatic Stress Disorder

1994	Eli Lilly & Co.	X Versus Placebo in Post-traumatic Stress Disorder
1998	SmithKline Beecham Pharmaceuticals	A 12-Week, Double-Blind, Fixed Dose Comparison of 20 and 40 mg Daily of X and Placebo in Patients Suffering from Post-traumatic Stress Disorder
1998-2000	Eli Lilly & Co.	X Versus Placebo in the Treatment of Post-traumatic Stress Disorder
2001-2002	Wyeth-Ayerst Research	A Double-Blind, Randomized, Placebo-Controlled, 3-Month Clinical Trial of X ER and Y in the Treatment of Post-traumatic Stress Disorder
2003-2004	Cephalon, Inc.	A 12-Month, Open-Label, Flexible-Dosage Study to Evaluate the Safety of X at Dosages up to 16mg/day in Adults with Chronic Post-Traumatic Stress Disorder
2007-2008	GlaxoSmithKline	A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dose Study Evaluating the Efficacy and Safety of the Neurokinin-1 Receptor Antagonist X in Post-traumatic Stress Disorder

Social Anxiety Disorder

1997-1998	SmithKline Beecham Pharmaceuticals	A Randomized, Double-Blind, Fixed Dose Comparison of 20, 40, and 60 mg Daily of Paroxetine and Placebo in the Treatment of Generalized Social Phobia No.29060/454
1998	Novartis Pharmaceuticals	A Multi center, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Dose-Range Finding Trial to Evaluate the Safety and Efficacy of 4 Doses of X in Patients with Social Phobia, Corporation
1998	Novartis Pharmaceuticals	A Randomized, Double-Blind, Dose-Range Finding Multi center Parallel-Group, Active and Placebo-Controlled Trial to Evaluate the Safety and Efficacy of X in Patients with Social Phobia

CLINICAL TRIAL EXPERIENCE (continued):

Social Anxiety Disorder (continued):

2000-2001	Wyeth-Ayerst Research	A Six-Month, Double-Blind, Placebo-Controlled Parallel-Group Comparison of X Extended Release Capsules and Placebo in Outpatients with Generalized Social Anxiety Disorder
2001-2002	Pfizer, Inc.	A Multi center Randomized Double-Blind, Placebo Controlled Trial of X for Acute Treatment of DSM-IV Generalized Social Phobia in Outpatients
2001-2002	Wyeth-Ayerst Research	A Double-Blind, Placebo-Controlled, Parallel-Group Comparison of X ER Capsules and Paroxetine in Outpatients with Generalized Social Anxiety Disorder
2001-2002	Wyeth-Ayerst Research	A Double-blind, Placebo Controlled Study of a Flexible Dose of X ER in Adolescent Outpatients with Generalized Social Anxiety
2002-2003	Wyeth-Ayerst Research	A Double-Blind, Placebo-Controlled Study of Flexible Dose of X ER in Adolescent Outpatients with Generalized Social Anxiety Disorder

2003	UCB Pharma, Inc.	A Multi center Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Assess the Efficacy and Safety of X Versus Placebo for the Treatment of Social Anxiety Disorder (Generalized Type)
2005	GlaxoSmithKline	A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Forced Dose Titration Study Evaluating the Efficacy and Safety of X and Paroxetine in Subjects with Social Anxiety Disorder
2006-2007	GlaxoSmithKline	A 12 Week Flexible Dose Study of X, Placebo and Active Control (Paroxetine) in the Treatment of Social Anxiety Disorder
2008-2009	Avera	A Phase 2, Double-Blind, Placebo-Controlled Trial to Investigate the Safety and Efficacy of X in Subjects with Social Anxiety Disorder

Opioid Induced Constipation (OIC)

2012	AstraZeneca	A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of X in Patients with Non-Cancer-Related Pain and Opioid-Induced Constipation (OIC)

CLINICAL TRIAL EXPERIENCE (continued):

Opioid Induced Constipation (OIC) (continued):

2013	Purdue Pharma	A Randomized, Double-Blind, Double-Dummy, Placebo-Controlled, Active-Controlled, Parallel-Group, Multi center Trial of x to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-Induced Constipation (Compared to x) in Opioid-experienced Subjects with Moderate to Severe Chronic Low Back Pain and a History of Opioid-Induced Constipation who Require Around-the-clock Opioid Therapy

Alzheimer's Disease

2010	Pfizer, Inc.	A Phase 2 Multi center, Double Blind, Placebo Controlled, Parallel Group Study of X in Subjects with Mild to Moderate Alzheimer's Disease
2010-2011	Sanofi-Aventis	A multinational, multi center, randomized, double-blind, parallel-group, placebo-controlled study of the effect on cognitive performance, safety, and tolerability of X at the doses of 0.5 mg, 2 mg, and 5 mg/day for 24 weeks in patients with mild to moderate Alzheimer's Disease on stable donepezil therapy
2012 - 2013	TauRx Therapeutics	Randomized, Double-Blind, Placebo-Controlled, Parallel-Group 18 Month Safety and Efficacy Study of X in Subjects with Mild Alzheimer's Disease
2013	Merck	A Randomized, Placebo Controlled, Parallel-Group, Double Blind Efficacy and Safety of X in Subjects with Mild to Moderate Alzheimer's Disease
2013	Accera	A 26-Week, Double-blind, Randomized, Placebo-controlled, Parallel-group Study to Investigate the Effects of Daily Administration of X in Participants with Mild to Moderate Alzheimer's Disease (AD) with Optional 26-Week Open-Label Extension
2016	Suven	A Phase 2A Multi center, Randomized, Double-Blind, Parallel Group, 26-Week, Placebo-Controlled Study of 50 mg and 100 mg of SUVN-502 in Subjects with Moderate Alzheimer's Disease Currently Treated with Donepezil Hydrochloride and Memantine Hydrochloride.

CLINICAL TRIAL EXPERIENCE (continued):

Attention Deficit Hyperactivity Disorder

2006-2007	Eli Lilly & Co.	Maintenance of Response After Open-Label Treatment with X in Adult Outpatients with Attention-Deficit/Hyperactivity Disorder (ADHD): A Placebo-Controlled, Randomized Withdrawal Study
2007-2008	Ortho-McNeil	A Placebo-controlled, Double-blind, Parallel-group, Individualized Dosing Study Optimizing Treatment of Adults with Attention Deficit Hyperactivity Disorder to an Effective Response with X
2007-2008	Ortho-McNeil	An Open-Label, Dose-Titration, Long-Term Safety Study to Evaluate X at Doses of 36 mg, 54 mg, 72 mg, 90 mg and 108 mg per day in Adults with Attention Deficit Hyperactivity Disorder
2012	Targacept	A Double-Blind, Randomized, Placebo-Controlled, Multi center, Fixed Dose Study to Assess Efficacy, Safety, and Tolerability of X in Adults with Inattentive-Predominant Attention
2010-2011	Otsuka	A Phase 2, Multi center, Randomized, Double-blind, Placebo Controlled Study of the Safety and Efficacy of X as Adjunctive Therapy in the Treatment of Adult Attention-Deficit/Hyperactivity Disorder
2010-2011	Novartis Pharmaceuticals	A 40-week, randomized, double-blind, placebo-controlled, multi center efficacy and safety study of X in the treatment of adult patients with childhood-onset ADHD

Panic Disorder

1992	Glaxo, Inc.	A Double-Blind, Placebo-Controlled Dose Escalation Study of the Safety and Efficacy of Oral Ondansetron in the Treatment of Patients with Panic Disorder, Protocol No. S3A-323
1994-1995	SmithKline Beecham Pharmaceuticals	A Double-Bind, Placebo-Controlled, Flexible Dosing Trial to Evaluate the Efficacy of Modified Release Paroxetine in the Treatment of Panic Disorder No. 29060/497
1997-1998	Interneuron Pharmaceuticals	Placebo-Controlled, Parallel Group Trial of Three Doses of Pagaclone in Patients with DSM-IV Panic Disorder IP456/004
2001-2002	Wyeth-Ayerst Research	A Double-Blind, Placebo-Controlled, Parallel-Group, Flexible-Dose Study of X Capsules in Adult Outpatients with Panic Disorder

CLINICAL TRIAL EXPERIENCE (continued):

Obsessive Compulsive Disorder

2002	Pfizer, Inc.	A Phase II, Twelve Week, Double Blind and Placebo Controlled Study to Evaluate the Safety and Efficacy of Two Doses X (1.5 mg and 3.0 mg) in Subjects with Obsessive Compulsive Disorder
2012	Transcept	A Multi-center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety with Obsessive Compulsive Disorder Who Have Not Adequately Responded to Treatment with a Selective Serotonin Reuptake Inhibitor Study

Eating Disorder

2003	Ortho-McNeil	The Effect of X on Bone Mineral Density in Pediatric Subjects with Anorexia Nervosa: A Double-Blind, Placebo-Controlled Study
2003-2005	Ortho-McNeil	A Multi center, Randomized, Double-Blind, Placebo-Controlled, Flexible-Dose Study to Assess the Safety and Efficacy of X in the Treatment of Moderate to Severe Binge-Eating Disorder Associated with Obesity
2011 - 2012	Shire	A Phase 2, Multi center, 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
2012 – 2013	Shire	Phase 3, Multi center, Randomized, Double-blind, Parallel-group, Placebo-controlled, Dose-optimization Study to Evaluate the Efficacy, Safety, and Tolerability of X in Adults aged 18-55 Years with Moderate to Sever Binge Eating Disorder.
2012 – 2013	Shire	A Phase 3, Multi center, Open-label, 12-month Extension Safety and Tolerability Study of X in the Treatment of Adults with Binge Eating Disorder

Polysomnograohic (PSG)

2003	Sanofi-Synthelabo	Evaluation of the Hypnotic Properties of X 12.5 mg and X 10 mg Marketed Product Compared to Placebo in Patients with Primary Insomnia. A Double-Blind, Randomized, Placebo-Controlled, Three Way Cross-Over Study

CLINICAL TRIAL EXPERIENCE (continued):

Polysomnograohic (PSG)

2003	Takeda	A Phase III Safety Study to Evaluate the Long-Term Effects of X on Endocrine Function in Adults with Chronic Insomnia
2003-2004	Cephalon, Inc.	A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study of the Efficacy and Safety of X (4, 6, 8, and 10 mg) Treatment in Adult Patients with Primary Insomnia
2004-2005	Cephalon, Inc.	A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Efficacy and Safety of X (150 mg/day) as Treatment for Adults with Residual Excessive Sleepiness Associated with Obstructive Sleep Apnea/Hypopnea Syndrome
2004-2006	Merck & Co.	A DoubleBlind, Randomized, PlaceboControlled, Multi center, 30Night Polysomnographic Study of X in Elderly Patients with Primary Insomnia
2005-2006	Merck & Co.	A DoubleBlind, Randomized, PlaceboControlled, Multi center, 30Night Polysomnographic Study of X in Adult Patients with Primary Insomnia
2007-2008	Sanofi-Aventis	Efficacy and safety of 2 mg/day X on Sleep Maintenance Insomnia: a 6-week, multi center, randomized, double-blind, placebo-controlled Polysomnographic study
2007-2008	Takeda	A Randomized, Double-Blind, Placebo-Controlled, Parallel, Proof of Concept Study to Evaluate the Effectiveness of X to Advance the Timing of Sleep in Individuals with Delayed Sleep Phase Syndrome (DSPS)
2008	Pfizer, Inc.	X Dose-Ranging Trial: A Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Multi center Outpatient Trial of X in Adults with Nonrestorative Sleep
2008-2009	Sanofi-Aventis	Efficacy and safety of X 5mg/day in insomnia characterized by sleep maintenance difficulties: a 6-week, randomized, double-blind, placebo-controlled, polysomnography study
2009-2010	Cephalon Inc.	A 12-Week, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Fixed-Dosage Study to Evaluate the Efficacy and Safety of X (50, 150 and 250 mg/day) as Treatment for Patients With Excessive Sleepiness Associated With Mild or Moderate Closed Traumatic Brain Injury

CLINICAL TRIAL EXPERIENCE (continued):

Polysomnograohic (PSG) *(continued):*

2010-2011	Pfizer Inc.	A Randomized, Double-Blind, Placebo-Controlled, 3-Way Crossover, Multi center Polysomnography Study of X and Y in Adults with Restless Legs Syndrome
2010-2011	Cephalon Inc.	A 12-Month, Open-Label Study to Evaluate the Safety, Tolerability, and Efficacy of X (150 and 250 mg/day) as Treatment for Patients with Excessive Sleepiness Associated with Mild or Moderate Closed Traumatic Brain Injury

Outpatient Sleep Disorders

1998	Wyeth-Ayerst Research	A Phase III, Multi center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Safety, Tolerance, and Efficacy Study of 10 and 20 mg Zaleplon, Protocol No. 0897A1-307US
1998	Wyeth-Ayerst Research	A Phase III, Multi center, Long-Term, Open-Label, Safety and Tolerance Study of 10 or 20 mg of Zolaplon Administered Once Daily for a Maximum of 360 Days in Adult Outpatients with Insomnia Protocol No. 0897A-312 US
1999	Merck & Co.	A Double-Blind, Placebo-Controlled Study of Patient Reported Sleep Effects of X in Older Patients with Chronic Primary Insomnia
2002	Sanofi-Synthelabo Research	Comparison of Efficacy and Safety of X 12.5 mg and Placebo in Patients with Primary Insomnia. A Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study
2002-2003	Neuroscience Bioscience	A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Study to Assess the Long-Term Safety and Efficacy of Two Dose Levels of X in Adult Patients with Primary Insomnia
2003-2005	Cephalon, Inc.	A 12-Month, Open-Label Study to Evaluate Safety and Efficacy of X at Dosages up to 10 mg/day in Adult Patients with Primary Insomnia
2003-2005	Cephalon, Inc.	A 12-Month, Open-Label Study to Evaluate Safety and Efficacy of X at Dosages up to 8 mg/day in Adult Patients with Primary Insomnia

CLINICAL TRIAL EXPERIENCE (continued):

Outpatient Sleep Disorders *(continued):*

2004-2005	Cephalon, Inc.	A 12-Month, Open-Label, Flexible-Dosage (100-250 mg/day) Extension Study of the Safety and Efficacy of X in the Treatment of Patients with Excessive Sleepiness Associated with Narcolepsy, Obstructive Sleep Apnea/Hypopnea Syndrome, or Chronic Shift Work Sleep Disorder
2004-2006	Merck & Co.	A Double-Blind, Randomized, Multi center, Placebo-Controlled, Parallel-Groups Efficacy and Safety Extension Study of X in the Treatment of Adult Outpatients With Primary Insomnia
2005-2007	Sanofi-Aventis	Evaluation of the Long-Term Efficacy and Safety of X 12.5-mg Compared to Placebo, When Both are Administered Over a Long-Term Period "As Needed", in Patients with Chronic Primary Insomnia. (A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multi center, Phase IIIb Clinical Study)
2006	Neurocrine Biosciences	A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Study to Assess the Efficacy and Safety of a Modified Release Formulation of X in Adult Primary Insomnia Patients with Sleep Maintenance Difficulties
2006-2007	Sanofi-Aventis	Efficacy and Safety of X 5 mg/day on Sleep Maintenance Insomnia: A 6-Week, Multi center, Randomized, Double-Blind, Placebo-Controlled Study
2006-2007	Sanofi-Aventis	Efficacy and Safety of X 5mg/day on Sleep Maintenance Insomnia: A 12-week Multi center, Randomized, Double-Blind, Placebo-Controlled Study
2006-2007	Arena	A randomized, double-blind, placebo controlled, 3-way cross-over study to evaluate effects of X in patients with insomnia
2007	Organon, Inc.	A six-week, double-blind, randomized, placebo-controlled, parallel group, efficacy and safety, sleep lab trial with X in patients with chronic primary insomnia
2007	Organon, Inc.	Fifty-two weeks, open-label extension trial to evaluate safety and efficacy of X in outpatients with chronic primary insomnia who completed Clinical Trial Protocol I or II

CLINICAL TRIAL EXPERIENCE (continued):

Outpatient Sleep Disorders *(continued):*

2008	Pfizer, Inc.	Refinement of Patient Reported Outcomes Instruments in Subjects with Insomnia Characterized by Nonrestorative Sleep
2008-2009	Organon, Inc.	A double-blind, randomized, parallel group, placebo-controlled sleep laboratory efficacy and safety study with X in elderly subjects with chronic primary insomnia
2009-2011	Merck & Co.	A Phase III, Multi center, Randomized, Double-Blind, Placebo-Controlled, Parallel- Group, Long-Term Safety Study of X in Patients with Primary Insomnia
2010-2011	Merck & Co.	A Phase IIb, Multi center, Randomized, Double-Blind, Placebo-Controlled, 2-Period Adaptive Crossover Polysomnography Study to Evaluate the Safety and Efficacy of X in Patients with Primary Insomnia
2010-2011	Cephalon Inc.	A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Tolerability of X Treatment (150 mg) in Improving Clinical Condition Late in the Shift and in Improving Functional and Patient-Reported Outcomes in Adult Patients With Excessive Sleepiness Associated With Shift Work Disorder

Fibromyalgia

2016	Daiichi Sanyo	A Randomized, Double-Blind, Placebo- and Active-Controlled Study of DS-5565 in Subjects with Pain Associated with Fibromyalgia, Phase III
2016	Daiichi Sanyo	An Open-Label Extension Study of DS-5565 for 52 Weeks in Pain Associated with Fibromyalgia, Phase III