Curriculum Vitae

Valentin Isacescu, MD
Principal Investigator/Subinvestigator

Signature: Valentin MD Date: 01/25/18

Licensure and Specialty

Licensure: Doctor of Medicine (MD), License #A68103, California
Specialty: Psychiatry, Board Eligible

Site Affiliation

North County Clinical Research
2122 S. El Camino Real, Suite 100
Oceanside, California 92054
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Current Hospital Affiliations

Aurora Behavioral Health Care
11878 Avenue of Industry
San Diego, California 92128

Professional Affiliation/Education

1980	Doctor of Medicine (MD), General Medicine Bucharest Institute of Medicine and Pharmacy, School of General Medicine Bucharest, Romania

Professional Experience

March 2007 to Present	Principal Investigator, Medical Director, and Owner North County Clinical Research, Oceanside, California
May 2005 to March 2007	Principal Investigator eStudySite, Oceanside, California
October 2003 to May 2005	Principal Investigator and Assistant Medical Director Optimum Health Services, Oceanside, California
March 2002 to October 2003	Principal Investigator and Subinvestigator Behavioral and Medical Research, San Diego, California
July 2001 to June 2002	Medical Director of Alcohol and Drug Treatment Program (ADTP) VA Medical Center, Department of Psychiatry, University of California, San Diego San Diego, California
July 2001 to June 2002	Assistant Clinical Professor Department of Psychiatry, University of California, San Diego San Diego, California
May 2001 to Present	Private Practice, Adult Psychiatry Oceanside, California

September 2000 to Present	Attending Physician, Scripps Drug and Alcohol Treatment Program Scripps Memorial Hospital, La Jolla, California
September 2000 to Present	Attending Physician Tri-City Medical Center, Oceanside, California
May 2001 to March 2002	Day Treatment and Outpatient Psychiatry Mental Health Systems (MHS), Pegasus West, San Diego, California
August 2000 to June 2001	Outpatient Psychiatry Scripps Outpatient Medical Health Unit, San Diego, California
January 2000 to August 2000	Subinvestigator Behavioral and Medical Research (BMR), San Diego, California
July 2000 to June 2001	Fourth Year Resident, Senior Resident in Alcohol and Drug Treatment Program (ADTP) VA Medical Center, University of California, San Diego, School of Medicine, Department of Psychiatry, San Diego, California
July 1999 to June 2000	Third Year Resident University of California, San Diego, School of Medicine, Department of Psychiatry, Psychiatry Residency Training Program, San Diego, California
April 1999 to June 1999	Four Weeks of Inpatient Psychiatry, Five Weeks of Child and Adolescent Psychiatry
July 1997 to June 1998	Second Year Resident University of California, San Diego, School of Medicine, Department of Psychiatry, Psychiatry Residency Training Program, San Diego, California
June 1996 to June 1997	First Year Resident University of California, San Diego, School of Medicine, Department of Psychiatry, Psychiatry Residency Training Program, San Diego, California
May 1988 to June 1994	Staff Research Associate University of California, Los Angeles, School of Medicine, Division of Clinical Immunology and Allergy, Laboratory of Cellular Immunology and Cytometry Los Angeles, California
May 1986 to April 1988	Doctor of Medicine (MD) and Post-Doctoral Fellowship (NIH Training) University of California, Los Angeles, School of Medicine, Department of Microbiology and Immunology, Los Angeles, California
October 1983 to September 1984	Doctor of Medicine (MD), Chief General Practice Calarasi County Outpatient Clinic, Roseti, Romania
September 1980 to September 1983	Doctor of Medicine (MD), Resident in Training Calarasi County Hospital, Calarasi, Romania

Other Professional Experience

June 1981 to May 1982
Research at the Allergy and Immunology Institute under the supervision of Professor Ervant Seropian MD in a study concerning the efficacy of the new Romanian drug, Bronhodin, a microbial suspension containing the most frequent microorganisms in the etiology of the allergic respiratory diseases, in general, and of infectious bronchial asthma, in particular

January 1980 to June 1980
Research in the Department of Infectious Diseases and Epidemiology under the supervision of Professor Marin Voiculescu MD in a project concerning the characteristics of obstructive jaundice in the neoplasm of hepatopancreatic ampulla (papilla of Vater) and the association between the clinical symptoms and the liver Computed Tomography (CT) scans in individual clinical cases

July 1979 to December 1979
Research in the Department of Obstetrics and Gynecology, Bucharest School of General Medicine, under the supervision of Professor Henriette Ciortoloman MD, in a project concerning uterine dynamics

January 1977 to June 1977
Research in the Department of Microbiology, Virology & Parasitology, Bucharest School of General Medicine, under the supervision of Professor Marasel Georgescu MD in the area of human neoplastic DNA viruses

Memberships

- American Psychiatric Association (APA), Member since 1997
- California Medical Association (CMA), Member since 1997
- San Diego Psychiatric Society (SDPS), Member since 1997
- American Medical Association (AMA), Member since 1989

Training and Certifications

2017 to Present NIDA Good Clinical Practices Training and Certification

2011 to Present Administration of the Columbia-Suicide Severity Rating Scale (CSSRS) Certification

2008 to Present NIH Protecting Human Research Participants Training and Certification

Sponsor/CRO provided training and certifications for the following rating scales:

- CGI-S/I
- DSM-IV (SCID)
- GAF
- HAM-A (SIGH-A)
- HAM-D-17
- IDS-C
- MADRS (SIGMA)
- YMRS

Publications

1. Plaeger-Marshall, S., Hausner, M.A., Isacescu, V., & Giorgi, J.V. CD-8 T-cell-mediated inhibition of HIV replication in HIV infected adults and children. AIDS Research and Human Retroviruses 1992; Aug, 8(8):1375-1376.

2. Chou, C.C., Gudeman, V., O'Rourke, S., Isacescu, V., Detels, R., Williams, G.J., Mitsuyasu, R.T., Giorgi, J.V., & the Los Angeles Multicenter AIDS Cohort Study. Phenotypically defined memory CD-4+ cells are not selectively decreased in chronic HIV disease. Journal of Acquired Immune Deficiency Syndrome, 1994 Jul,7(7):665-75.

3. Shau, H., Isacescu, V., Ibayashi, Y., Tokuda, Y., Golub, S.H., Fahey, J.L., & Sarna, G.P. A Pilot study of intralymphatic Interlukin-2. I. Cytotoxic and surface marker changes of peripheral blood lymphocytes. Journal of Biological Response Modifiers 1990 Feb, 9(1):71-80. Raven Press, Ltd., New York.

4. Plaeger-Marshall, S., Isacescu, V., O'Rourke, S., Bertolli, J., Bryson, Y.J., & Stiehm, E.R. T-cell activation in pediatric AIDS pathogenesis: three-color immunophenotyping. Clinical Immunology and Immunopathology, 1994 Apr, 71(1):19-26.

5. Schmid, I., Gayle, C.B., Jacobs, E.L., Isacescu, V., Neagos, N., Giorgi, J.V., & Glaspy, J.A. Alterations in phenotype and cell surface antigen expression levels of human monocytes: Differential response to in vivo administration of rhM-CSF or rhGM-CSF. Accepted for publication Jan. 24, 1995. Cytometry, 1995, 20:00-00.

6. Storek, J., Ferrara, S., & Isacescu, V. Blood B cell subpopulations. The effect of narrow versus wide forward scatter x side scatter gating [letter]. Journal of Immunological Methods, 1992, Nov 25, 156(1):129-133.

7. Clement, L.T., Isacescu, V., Champlin, R., Giorgi, J.V., & Bradley, G. Differentiation of CD4+ T cells subpopulations after allogeneic bone marrow transplantation. To be published.

8. Clement, L.T., Isacescu, V., Feig, S., & Bradley, G. Phenotypic and functional characteristics of the CD4+ T cells appearing after bone marrow transplantation for the immunologic reconstitution of severe combined

immunodeficiency. To be published.

Abstracts

1. Plaeger-Marshall, S., **Isacescu**, V., Bertolli, J., O'Rourke, S., Aziz, N., Dillon, M., Wafer, D., Giorgi, J.V., Boyer, P.J., & Bryson, Y.J. Serial studies of immune activation in HIV+ and control pregnant women. Abstract published in Journal of Cellular Biochemistry. Supplement 17E, pp.99, 1993.

2. Clement, L.T., **Isacescu**, V., Champlin, R., Giorgi, J.V., & Bradley, G. Differentiation of CD4+ T cells subpopulations after allogeneic bone marrow transplantation. Abstract published in Clinical Research. Vol. 38:432A, 1990.

3. Clement, L.T., **Isacescu**, V., Feig, S., & Bradley, G. Phenotypic and functional characteristics of the CD4+ T cells appearing after bone marrow transplantation for the immunologic reconstitution of severe combined immunodeficiency. Abstract published in Pediatric Research. Vol. 27:155A, 1990.

Time Periods Not Listed Above

July 1998 to April 1999
I studied full time for Step 3 of the United States Medical Licensing Examination (U.S.M.L.E.), which I passed in December1998. This allowed me to apply for licensure in the State of California, which I obtained in April 1999.

June 1994 to June 1996
I resigned from my position at U.C.L.A. in order to dedicate my full attention to study for Step 2 of the U.S.M.L.E., which I passed in March 1995. I also enrolled in the National Resident Matching Program (N.R.M.P.) and started the application process for the first year of residency program (PGY-1).

January 1985 to February 1986
In January 1985 I entered the U.S.A. as a political refugee. That year I settled in and began gathering materials and studying for the (U.S.M.L.E.) formerly offered as E.C.F.M.G and F.L.E.X. examinations. I also began to search for a job, which I found in March 1986, at U.C.L.A.

Languages

- English
- Romanian
- French

Other Clinical Trial Experience (Prior to North County Clinical Research)

Alzheimer's Disease

A randomized, multi center, double blind, placebo controlled, 18 month study of the efficacy of XXXX in patients with mild to moderate dementia of the Alzheimer's type

A phase II double blind, randomized, dose-ranging, placebo-controlled, multi-center, safety and efficacy evaluation of three doses of XXXX in patients with mild to moderate dementia of the Alzheimer's type

A randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of XXXX in subjects with mild cognitive impairment (MCI) clinically at risk for development of clinically probable Alzheimer's disease

A randomized, double-blind, placebo-controlled evaluation of the safety and efficacy of XXXX in patients with mild to moderate dementia of the Alzheimer's type

A long-term extension study evaluating the safety and tolerability of BID and QD administration of XXXX in patients with mild to moderate dementia of the Alzheimer's type

Attention Deficit Hyperactivity Disorder

A phase 3, randomized, multi-center, double-blind, parallel-group, placebo-controlled study of XXXX in children aged 6-12 with attention deficit hyperactivity disorder (ADHD)

A two-year, open-label, and single-arm study of XXXX 30 mg, 50 mg, or 70 mg per day in children aged 6-12 years with attention deficit hyperactivity disorder (ADHD)

A phase II, open-label co-administration study of XXXX (extended-release XXXX XXXX) and XXXX in children and adolescents aged 6-17 with attention-deficit hyperactivity disorder (ADHD)

A phase III, randomized, double-blind, multicenter, parallel-group, placebo-controlled safety and efficacy study of XXXX(extended-release XXXX XXXX) in children and adolescents aged 6-17 with attention-deficit hyperactivity disorder (ADHD)

A phase III, open-label study of XXXX(extended-release XXXX XXXX) in children and adolescents aged 6-17 with attention-deficit hyperactivity disorder (ADHD)

A double-blind, placebo-controlled, parallel-group study of XXXX in adults with attention deficit hyperactivity disorder

A double-blind, open-label, parallel-group study of XXXX XR in adults with attention deficit hyperactivity disorder (extension)

A phase III randomized, double-blind comparison of placebo and XXXX XXXX in adult outpatients with DSM-IV attention deficit hyperactivity disorder

Multi-centre, double-blind, three arm, parallel group study comparing the efficacy of immediate release XXXX (XXXX) and modified release XXXX with placebo in children with attention-deficit hyperactive disorder

Bipolar Disorder

Placebo-controlled XXXX monotherapy in the treatment of bipolar I depression

A confirmatory multicenter, double-blind, randomized, placebo-controlled study of the use of XXXX XXXX (XXXX) in the treatment of patients with bipolar depression

Randomized, double-blind, placebo-controlled study to explore the efficacy and safety of XXXX long-acting intramuscular injectable in the prevention of mood episodes in bipolar I disorder, with open-label extension

A multi-center, randomized, parallel-group, double-blind, phase III comparison of the efficacy and safety of XXXX XXXX to placebo when used as adjunct to mood stabilizers in the maintenance treatment of bipolar I disorder in adult patients

XXXX versus Placebo as add-on treatment in subjects with bipolar disorder in the outpatient setting

A phase III, randomized, placebo controlled, double blind trial evaluating the safety and efficacy of sublingual XXXX vs. XXXX and placebo in in-patients with an acute manic episode

A double-blind, 9 week extension study evaluating the safety and maintenance of effect of XXXX vs. XXXX in the treatment of subjects with acute mania

Chronic Low Back Pain

A multi-center, standard of care-controlled study to evaluate the long-term safety of XXXX for the treatment of chronic low back pain

Generalized Anxiety Disorder

A double-blind, randomized, prospective, study to evaluate adjunctive XXXX versus adjunctive placebo in generalized anxiety disorder sub-optimally responsive to standard psychotropic therapy

A double-placebo and active controlled, dose-ranging study of XXXX, 3 doses (5, 15, 50mg per day) and XXXX (3mg/day) in out-patients with generalized anxiety disorder

An open-label, blinded-rater, randomized, 10-week study to evaluate the safety and efficacy of flexible doses of XXXX (XXXX XXXX) with XXXX (XXXX) as a positive control in patients with generalized anxiety disorder

Insomnia

Randomized, double-blind, placebo-controlled parallel study of the efficacy and safety of XXXX in the treatment of adult subjects with primary insomnia followed by optional open-label

A phase III, randomized, double blind, placebo-controlled, outpatient study to assess the efficacy and safety of two dose levels of modified release formulation of XXXX in elderly primary insomnia patients with sleep maintenance difficulties

A double-blind, multicenter, placebo-controlled, parallel-groups efficacy and safety extension study of XXXX in the treatment of adult outpatients with primary insomnia

A 12 month, randomized, double blind, placebo controlled, parallel groups, multi center long term safety study of XXXX in the treatment of elderly outpatients with primary insomnia

A randomized, double-blind, placebo-controlled study to assess the subjective response to treatment with XXXX (XXXX) in adult subjects with chronic insomnia by utilizing an interactive voice response system (IVRS) for collecting diary data

A randomized, double-blind, placebo-controlled, dose-response study to assess the efficacy and safety of a modified release formulation of XXXX in elderly patients with chronic sleep maintenance insomnia

A randomized, double-blind, placebo-controlled, dose-response study to assess the efficacy and safety of modified release formulation of XXXX in elderly patients with chronic sleep maintenance insomnia

Phase III randomized, double-blind, placebo-controlled, parallel-group, multicenter study to assess the efficacy and safety of XXXX in adults with primary insomnia

Comparison of efficacy and safety of XXXX 6.25 mg and placebo in elderly patients with primary insomnia a double-blind, randomized, placebo-controlled, parallel-group study

Phase III, randomized, double-blind, placebo-controlled, parallel-group, multicenter study to assess the efficacy and safety of a modified release formulation of XXXX in elderly primary insomnia patients with sleep maintenance difficulties

A randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of 12 weeks of XXXX (XXXX) therapy at a dose of 200 mg as treatment for adults with excessive sleepiness associated with chronic shift work sleep disorder, followed by a 12-month open-label extension period

Major Depressive Disorder

The study of XXXX plus XXXX in combination for treatment-resistant depression without psychotic features

A double-blind, randomized, prospective trial to evaluate the efficacy and safety of adjunctive XXXX versus placebo in subjects with major depressive disorder with suboptimal response to standard antidepressant therapy

A double-blind, multicenter, randomized, placebo-controlled, parallel group study of efficacy and safety of XXXX and XXXX in subjects who suffer from major depressive disorder with atypical features

A double-blind, multi-center extension trial in subjects who suffer from major depressive disorder with atypical features who participated in the XXXX placebo-controlled study of XXXX

A multi-centre, randomized, double-blind, parallel-group, placebo-controlled, flexible dose study to evaluate the efficacy, safety and tolerability of extended-release XXXX XXXX (150mg-300mg once daily) in elderly subjects with major depressive disorder

A multicenter, double-blind, randomized, placebo-controlled comparison of the effects on sexual functioning of extended-release XXXX XXXX and XXXX in outpatients with moderate to severe major Depression over an eight-week treatment period

A double-blind, placebo-controlled, dose-ranging study of fixed-doses of oral XXXX and XXXX in the treatment of outpatients with moderate depression

A double-blind, placebo-controlled, multicenter study of the long term efficacy of XXXX in the maintenance of antidepressant effect in geriatric outpatients with major depressive disorder

The addition of XXXX to XXXX in treatment resistant depression without psychotic features

Double-blind fixed dose comparison of the safety and efficacy of 20 mg/day XXXX and 225 mg/day XXXX in the treatment of major depressive disorder

Study to evaluate the efficacy, safety and maintenance effect of XXXX augmentation of SSRI monotherapy in young and older adult patients with unipolar treatment resistant depression

Migraine

Single-dose, double-blind, placebo-controlled, randomized, parallel-design, oral dose (0.2mg, 0.4mg, 0.8 mg, and 1.2 mg) response study of XXXX in the treatment of acute migraine headache with or without aura

Single-dose, open –label extension, randomized, parallel-design, oral dose response study of XXXX in the treatment of acute migraine headache with or without Aura

Panic Disorder

Double-blind, placebo-controlled, parallel-group, flexible-dose study of XXXX extended-release capsules in adult outpatients with panic disorder

Schizophrenia/Schizoaffective Disorder

Use of XXXX as a therapy for side effects in patients with schizophrenia or schizoaffective disorder treated with antipsychotics protocol for Study XXXX

A randomized, double-blind, placebo and active controlled, parallel-group, dose response study to evaluate the efficacy and safety of two fixed dosages of extended release XXXX XXXX (6 and 12mg/day) and XXXX (10mg/day), with open-label extension, in the treatment of subjects with schizophrenia

A multi-center, double-blind, randomized comparison of the efficacy and safety of sustained-release formulation XXXX XXXX (XXXX) and placebo in the treatment of patients with schizophrenia

A placebo- and positive-controlled, randomized study evaluating QT and QTc intervals following administration of immediate-release XXXX in subjects with schizophrenia or schizoaffective disorder

Insulin sensitivity in patients with schizophrenia or schizoaffective disorder treated with XXXX and XXXX

Phase 3: A multi-center, double–blind, placebo-controlled, randomized, parallel group evaluation of the efficacy of a flexible dose of XXXX versus placebo as add-on therapy in schizophrenia

A randomized, double-blind, placebo-controlled, parallel-group, dose response study to evaluate the efficacy and safety of 3 fixed doses (25 mg eq, 50 mg eq, and 100 mg eq) of XXXX XXXX in subjects with schizophrenia

A randomized, double-blind, placebo- and active-controlled, parallel group, dose-response study to evaluate the efficacy and safety of 2 fixed dosages of extended release XXXX XXXX (6 and 12 mg/day) and XXXX (10 mg.day), with open-label extension, in the treatment of subjects with schizophrenia

An open-label extension to study: A randomized, double-blind, placebo- and active controlled, parallel group, dose response study to evaluate the efficacy and safety of 2 fixed dosages of extended release XXXX XXXX (6 and 12 mg/day) and XXXX (10 mg.day), with open-label extension, in the treatment of subjects with schizophrenia, 52 week extension study

Chronic dosing for one year XXXX versus XXXX in the treatment of schizophrenia

A randomized, double-blind, placebo-controlled, XXXX referenced, dose finding study of XXXX in the treatment of schizophrenia

A randomized, open-label, rater-blinded, assessment of optimal treatment change strategy to XXXX for patients intolerant of XXXX (XXXX Rescue Study)

Social Anxiety Disorder

Double-blind, placebo-controlled, parallel-group, flexible-dose study of XXXX in adolescent outpatients with social anxiety disorder

Miscellaneous

The assessment of XXXX for the treatment of XXXX-associated weight gain in patients with schizophrenia, schizophreniform disorder, schizoaffective disorder, and bipolar I disorder

North County Clinical Research

Clinical Research Trials

Valentin Isacescu, MD

Year Started	Phase	Indication	Protocol Title
2017	N/A	Dyskinesia – Registry Study	Real-world evaluation screening study and registry of dyskinesia in patients taking antipsychotic agents (XXXX)
2017	Phase 2	Attenuated Pychosis	A phase II randomised, double-blind, placebo-controlled study to evaluate the efficacy, safety, and tolerability of orally administered XXXX during a 52-week treatment period as an early intervention in patients with attenuated psychosis syndrome
2017	Phase 2	Post-Traumatic Stress Disorder	A phase 2, multicenter, randomized, double-blind, placebo- and active-controlled trial of XXXX (1 - 3 mg/day) as monotherapy or as combination therapy in the treatment of adults with post-traumatic stress disorder
2017	Phase 3	Alzheimer's Disease	A placebo-controlled, double-blind, parallel-group, 24-month study to evaluate the efficacy and safety of XXXX in subjects with early Alzheimer's Disease
2017	Phase 3b	Major Depressive Disorder	A phase 3b efficacy and safety of adjunctive XXXX in treatment refractory major depressive disorder
2016	N/A	Mild Cognitive Impairment and Mild Dementia due to Alzheimer's Disease – Cohort Study	Longitudinal cohort study of resource use and cost of mild cognitive impairment and mild dementia due to Alzheimer's Disease in the United States (XXXX)
2016	Phase 2/3	Major Depressive Disorder	A randomized, double-blind, active-controlled trial to assess the efficacy and safety of XXXX administered orally to subjects with treatment resistant major depressive disorder
2016	Phase 3	Major Depressive Disorder	A phase 3 multicenter extension study of XXXX to assess the long-term safety and tolerability of XXXX for the adjunctive treatment of major depressive disorder in adults who have an inadequate response to antidepressant therapy
2016	Phase 3	Migraine	A phase 3, multicenter, randomized, double-blind, placebo-controlled single attack study to evaluate the efficacyy, safety, and tolerability of oral XXXX in the acute treatment of migraine
2016	Phase 3	Migraine	A multicenter, randomized, open-label extension study to evaluate the long-term safety and tolerability of oral XXXX in the acute treatement of migraine with or without aura

2016	Phase 3	Otitis Externa	A 1-month, prospective, randomized, double-blind, sham-controlled, multicenter, phase 3 study of XXXX given as single Administration for treatment of acute otitis externa
2016	Phase 3	Schizophrenia	Interventional, randomised, double-blind, active-controlled, fixed-dose study of XXXX in patients with treatment-resistant schizophrenia (XXXX)
2016	Phase 3	Schizophrenia	Interventional, open-label, flexible-dose, long-term safety study of XXX in adult patients with schizophrenia (XXXX)
2016	Phase 4	Chronic Pain	A randomized, double-blind, placebo-controlled, clinical trial of structured opioid discontinuation versus continued opioid therapy in suboptimal and optimal responders to high-dose long-term opioid analgesic therapy for chronic pain
2015	Phase 2a	Major Depressive Disorder	A phase 2a randomized, double-blind, placebo-controlled, parallel-group, multi-center study investigating the efficacy, safety, and tolerability of XXXX in subjects with major depressive disorder with anxious distress
2015	Phase 3	Major Depressive Disorder – Questionnaire Study	A non-interventional study of subjects who have participated in ALK5461-208, a study of adjunctive treatment of major depressive disorder
2015	Phase 3	Opioid Use Disorder	A phase 3 study to evaluate the safety, tolerability, and efficacy of XXXX for use in conjunction with XXXX in adults with opioid use disorder prior to first dose of XXXX
2015	Phase 3	Opioid Use Disorder	A phase III, randomized, double-blind, active-controlled, parallel-group, multi-center trial assessing the efficacy and Safety of a Once-Weekly and Once-Monthly, Long-Acting subcutaneous injectable depot of XXXX (XXXX) in treatment of adult outpatients with opioid use disorder
2015	Phase 3	Opioid Use Disorder	A randomized, double-blinded, placebo-controlled, multicenter study to assess the efficacy, safety, and tolerability of multiple subcutaneous injections of depot XXXX (XXXX [100 mg and 300 mg]) over 24 weeks in treatment-seeking subjects with opioid use disorder
2015	Phase 3	Opioid Use Disorder	An open-label, long-term safety and tolerability study of depot XXXX (XXXX) in treatment-seeking subjects with opioid use disorder
2015	Phase 4	Major Depressive Disorder	12-week, randomized, double-blind, controlled evaluation followed by an open-label 12-week follow-up period of the impact of XXXX XXXX on response to psychotropic treatment in outpatients suffering from a major depressive disorder (MDD) and having had – within the current episode – an inadequate response to at least one psychotropic medication included in XXXX XXXX
2015	Phase 4	Schizophrenia	Safety and tolerability of initiating XXXX XXXX in subjects with schizophrenia who are inadequately treated with XXXX XXXX

2015	Phase 4	Schizophrenia Caregiver Training	A 12-month randomized, open-label study of caregiver psycho-education and skills training in patients recently diagnosed with schizophrenia, schizoaffective disorder, or schizophreniform disorder and receiving XXXX XXXX or oral antipsychotic treatment
2014	N/A	Major Depressive Disorder Observational Study	A prospective, longitudinal, observational study to evaluate potential predictors of relapse in subjects with major depressive disorder who have responded to antidepressant treatment
2014	Phase 2	Treatment Resistant Depression	A phase 2, multicenter, randomized, double-blind, placebo-controlled study to assess the efficacy, safety, and tolerability of XXXX (XXXX XXXX XXXX XXXX/XXXX XXXX) as an adjunctive therapy in patients with major depressive disorder with an inadequate response to antidepressant treatment
2014	2b	Influenza	A phase 2b, randomized, double-blind, placebo-controlled, parallel-group, multicenter study of 2 dose levels of XXXX administered as monotherapy and one dose level of XXXX administered in combination with XXXX for the treatment of acute uncomplicated seasonal influenza A in adult subjects
2014	Phase 3	Attention Deficit Hyperactivity Disorder	A randomized, double-blind, multicenter, placebo-controlled, parallel-group, efficacy and safety study of 2 doses of XXXX in adults with attention deficit hyperactivity disorder (ADHD)
2014	Phase 3	Bipolar I Disorder	A randomized, double-blind, placebo-controlled, phase 3 study to evaluate the efficacy and safety of once a day, XXXX tablet 0.1 mg and 0.4 mg as an adjunctive therapy to treatment-as-usual in the maintenance treatment of bipolar I disorder in adult subjects
2014	Phase 3	Generalized Anxiety Disorder	A randomized double-blind, placebo controlled, flexible and fixed dose, parallel group study of extended-release XXXX (XXXX) for the treatment of generalized anxiety disorder (GAD)
2014	Phase 3	Major Depressive Disorder	A phase 3 efficacy and safety study of XXXX for the adjunctive treatment of major depressive disorder
2014	Phase 3	Major Depressive Disorder	A phase 3 multicenter study of the long-term safety and tolerability of XXXX for the adjunctive treatment of major depressive disorder in adults who have an inadequate response to antidepressant therapy
2014	Phase 3	Neuropathic Pain	A randomized double-blind placebo controlled parallel group study of the efficacy and safety of XXXX (BID) in subjects with post-traumatic peripheral neuropathic pain
2014	Phase 3	Tardive Dyskinesia	A randomized, double-blind, placebo-controlled, fixed-dose study of XXXX (XXXX) for the treatment of moderate to severe tardive dyskinesia
2014	Phase 3	Tardive Dyskinesia	An open-label, long-term safety study of XXXX (XXXX) for the treatment of moderate to severe tardive dyskinesia

2014	Phase 3	Tardive Dyskinesia	A phase 3, randomized, double-blind, placebo-controlled, parallel, fixed-dose study to assess the efficacy, safety, and tolerability of XXXX for the treatment of tardive dyskinesia
2014	Phase 4	Opioid Dependence	A randomized, double-blind, double-dummy, active-controlled multicenter study of adult outpatients with opioid dependence transitioned from a daily maintenance dose of 8 mg or less of sublingual XXXX or XXXX/XXXX to four XXXX subdermal implants
2013	Phase 2	Cocaine Dependency	A 12-week, multicenter, randomized, double-blind, placebo-controlled, parallel-group study to evaluate the efficacy and safety of once-weekly intra-muscular injections of XXXX (150 mg/week or 300 mg/week) as treatment for facilitation of abstinence in cocaine-dependent subjects
2013	Phase 2	Schizophrenia	A phase 2, randomized, multicenter, safety, tolerability, and dose-ranging study of XXXX, a component of XXXX, in adults with schizophrenia treated with XXXX
2013	Phase 3	Major Depressive Disorder	A phase 3, long-term, open-label study of safety and tolerability of XXXX as adjunctive therapy in major depressive disorder
2013	Phase 3	Major Depressive Disorder with Psychotic Features Diagnosis Screening	A study to confirm a diagnosis of major depressive disorder with psychotic features and screen potential patients for study XXXX
2013	Phase 3	Opioid Dependence	A randomized, blinded, active-controlled non-inferiority study of the efficacy and safety of XXXX for the induction of treatment of opioid dependence
2013	Phase 3	Opioid Dependence	Phase III - A multi-center, open-label, 24-week, follow-up study to assess safety, efficacy and treatment adherence for maintenance treatment of opioid dependence with XXXX
2013	Phase 3	Opioid-Induced Constipation	A multicenter, randomized, double-blind, placebo-controlled, phase 3 study to evaluate the efficacy and safety of XXXX for the treatment of opioid-induced constipation in adults taking opioid therapy for chronic non-cancer pain
2013	Phase 3	Opioid-Induced Constipation	A multicenter, randomized, double-blind, placebo-controlled, phase 3 study to evaluate the long-term safety and tolerability of XXXX for the treatment of opioid-induced constipation in adults taking opioid therapy for chronic non-cancer pain
2013	Phase 3	Schizophrenia	A phase 3, multicenter, extension of Study XXXX to assess the long-term safety and durability of effect of XXXX in subjects with stable schizophrenia
2013	Phase 3b	Schizophrenia	An exploratory, multicenter, open-label, monotherapy, flexible-dose XXXX (XXXX) trial in adults with early episode schizophrenia

2013	Phase 4	Adolescent Smoking Cessation	A twelve week, randomized, double blind, placebo controlled, parallel group, dose ranging study with follow up evaluating the safety and efficacy of XXXX for smoking cessation in healthy adolescent smokers
2012	Phase 2	Bipolar I Disorder	A prospective, randomized, double-blind, placebo-controlled, phase 2 safety and efficacy study of oral XXXX as an adjunctive maintenance treatment in patients with bipolar I disorder
2012	Phase 3	Bipolar 1 Disorder with Depression	A randomized, double-blind, placebo-controlled, phase 3 study to evaluate the efficacy and safety of once a day, XXXX (XXXX) tablet for sublingual administration (XXXX Tablet) 0.1 mg and 0.4 mg as an adjunctive therapy in the treatment of acute depressive episodes associated with bipolar 1 disorder in adult subjects
2012	Phase 3	Bipolar 1 Disorder with Depression	A randomized, double-blind, placebo-controlled, phase 3 study to evaluate the efficacy and safety of once a day, XXXX 0.1 and 0.4 mg as an adjunctive therapy to treatment-as-usual in the maintenance treatment of bipolar 1 disorder in adult subjects
2012	Phase 3	Bipolar I Disorder	A 52-week, multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety, and tolerability of an intramuscular depot formulation of XXXX (XXXX) as maintenance treatment in patients with bipolar I disorder
2012	Phase 3	Bipolar I Disorder	A 52-week, multicenter, open-label study to evaluate the effectiveness of an intramuscular depot formulation of XXXX (XXXX) as maintenance treatment in patients with bipolar I disorder
2012	Phase 3	Low Back Pain/Opioid Induced Constipation	A randomized, double-blind, double-dummy, placebo-controlled, active-controlled, parallel-group, multicenter trial of XXXX/XXXX controlled-release tablets (XXXX) to assess the analgesic efficacy (compared to placebo) and the management of opioid-induced constipation (compared to XXXX controlled-release tablets (XXXX) 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
2012	Phase 3	Major Depressive Disorder	A phase 3, double-blind, placebo- controled study of XXXX as adjunctive therapy in major depressive disorder
2012	Phase 3	Major Depressive Disorder	Phase 3, multicenter, randomized, double-blind, parallel-group, placebo-controlled, flexible dose titration, efficacy and safety study of XXXX in combination with an antidepressant in the treatment of adults with major depressive disorder with inadequate response to prospective treatment with an antidepressant
2012	Phase 3	Major Depressive Disorder	A phase 3, open-label, multicenter, 12-month extension safety and tolerability study of XXXX 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

2012	Phase 3	Opioid-Induced Constipation	A randomized, double-blind, placebo-controlled study to assess the efficacy and safety of XXXX in patients with non-cancer-related pain and opioid-induced constipation (OIC)
2012	Phase 3	Schizophrenia	A phase 3, multicenter, extension of study XXXX to assess the long-term safety and durability of effect of XXXX in subjects with stable schizophrenia
2012	Phase 3	Schizophrenia	A phase 3, multicenter, randomized, double-blind, placebo-controlled study of the efficacy and safety of XXXX in subjects with acute exacerbation of schizophrenia
2012	Phase 3	Schizophrenia	A randomized, double-blind, placebo-controlled, parallel, 12-week, phase 3 study of 2 doses of an XXXX XXXX XXXX XXXX XXXX (XXXX) or placebo as an adjunctive pro-cognitive treatment in schizophrenia subjects on chronic stable atypical antipsychotic therapy
2012	Phase 3	Schizophrenia	A multicenter 40-week extension study to evaluate the safety and clinical effects of prolonged exposure to 1 and 2 mg doses of XXXX, an XXXX XXXX XXXX XXXX XXXX, as an adjunctive pro-cognitive treatment in subjects with schizophrenia on chronic stable atypical antipsychotic therapy
2012	Phase 3	Schizophrenia	A randomized, multicenter, double-blind, non-inferiority study of XXXX XXXX 3 month and 1 month formulations for the treatment of subjects with schizophrenia
2012	Phase 3	Schizophrenia	A 12-week, phase 3, multicenter, randomized, double blind, placebo-controlled trial of XXXX intramuscular depot (XXXX) in the acute treatment of adults with schizophrenia
2012	Phase 3	Schizophrenia	A 26-week, multicenter, open-label, extension study of XXXX intramuscular depot (XXXX) in patients with schizophrenia
2012	Phase 4	Smoking Cessation Cardiac Assessments	A phase 4, non-treatment follow-up for cardiac assessments following use of smoking cessation treatments in subjects with and without a history of psychiatric disorders
2011	Phase 2	Gout	A randomized, double-blind, dose-response study of the safety and efficacy of oral XXXX added to XXXX in subjects with gout who have not adequately responded to XXXX monotherapy
2011	Phase 2	Major Depressive Disorder	A randomized, double-blind, placebo-controlled, parallel group, phase 2 study of XXXX in subjects with major depressive disorder
2011	Phase 2	Schizophrenia	Phase III, multi-center, randomized, 12-week, double-blind, parallel-group, placebo-controlled study to evaluate the efficacy and safety of XXXX in patients with sub-optimally controlled symptoms of schizophrenia treated with antipsychotics followed by a 40-week double-blind, parallel-group, placebo-controlled treatment period

2011	Phase 2	Schizophrenia	A phase III, multi-center, randomized, 24 week, double-blind, parallel-group, placebo-controlled study to evaluate efficacy and safety of XXXX in stable patients with persistent, predominant negative symptoms of schizophrenia treated with antipsychotics followed by a 28 week, double-blind treatment period
2011	Phase 3	Major Depression Associated with Bipolar I Disorder	A double-blind, placebo-controlled, parallel-group, fixed-dosage study to evaluate the efficacy and safety of XXXX Treatment (150 and 200 mg/day) as adjunctive therapy in adults with major depression associated with bipolar I disorder
2011	Phase 3	Major Depression Associated with Bipolar I Disorder	A 6 month, open-label, flexible-dosage (150 to 200 mg/day) extension study of the safety and efficacy of XXXX treatment as adjunctive therapy in adults with major depression associated with bipolar I disorder
2011	Phase 3	Major Depressive Disorder	A phase 3, long-term, open-label, flexible-dose, extension study evaluating the safety and tolerability of XXXX (15 and 20 mg) in subjects with major depressive disorder
2011	Phase 3	Major Depressive Disorder	A phase 3, randomized, double-blind, parallel-group, placebo-controlled, fixed-dose study comparing the efficacy and safety of 2 doses (10 and 15 mg) of XXXX in acute treatment of adults with major depressive disorder
2011	Phase 3	Opioid-Induced Bowel Dysfunction	A multicenter, randomized, placebo-controlled, double-blinded study of the efficacy and safety of XXXX in subjects with opioid-induced bowel dysfunction
2011	Phase 3	Opioid-Induced Constipation	An open-label 52-week study to assess the long-term safety of XXXX-XX in opioid-induced constipation (OIC) in patients with non-cancer-related pain
2011	Phase 3	Schizophrenia	An open-label, multicenter, rollover, long-term study of XXXX intramuscular depot in patients with schizophrenia
2011	Phase 3b	Schizophrenia	A multicenter, open-label study to assess hospitalization rates in adult subjects with schizophrenia treated prospectively for 6 months with XXXX IM Depot compared with 6-month retrospective treatment with oral antipsychotics in a naturalistic community setting in the united states
2011	Phase 4	Schizophrenia	A 12-week, randomized, multi-center, open-label, XXXX, (12-24mg/day), flexible dose study assessing efficacy, safety and tolerability of two switch approaches in schizophrenia patients currently receiving XXXX, XXXX or XXXX
2011	Phase 4	Smoking Cessation	A phase 4, randomized , double-blind, active and placebo-controlled, multicenter study evaluating the neuropsychiatric safety and efficacy of 12 weeks XXXX XXXX 1mg BID and XXXX XXXX 150mg BID for smoking cessation in subjects with and without a history of pschiatric disorders

2010	Phase 3	Attention Deficit/Hyperactivity Disorder with Insomnia	A randomized, placebo-controlled, double-blind, fixed-dose study of the efficacy and safety of XXXX in children (6 to 11 years) and adolescents (12 to 17 years) with attention-deficit/hyperactivity disorder-associated insomnia
2010	Phase 3	Attention Deficit/Hyperactivity Disorder with Insomnia	A long-term, open-label, safety study of XXXX in children (6 to 11 years) and adolescents (12 to 17 years) with attention-deficit/hyperactivity disorder-associated insomnia
2010	Phase 3	Major Depressive Disorder	A multicenter, randomized, double-blind, parallel group, placebo-controlled, phase III, efficacy and safety study of 3 fixed dose groups of XXXX (XXXX) as an adjunct to an antidepressant in patients with major depressive disorder who exhibit an inadequate response to antidepressant therapy
2010	Phase 3	Opioid Addiction	A phase 3, six-month, open-label re-treatment study of XXXX in opioid addiction
2010	Phase 3	Opioid Dependence	A randomized, placebo and active-controlled, multi-center study of XXXX in patients with opioid dependence
2010	Phase 4	Schizophrenia	A fifteen-month, prospective, randomized, active-controlled, open-label, flexible dose study of XXXX XXXX compared with oral antipsychotic treatment in delaying time to treatment failure in adults with schizophrenia who have been incarcerated
2009	Phase 2	Alcohol Dependence	A phase 2, multi-center, randomized, double-blind, placebo-controlled, adaptive study of the safety and efficacy of XXXX in adults with alcohol dependence
2009	Phase 2b	Chronic Low Back Pain	A randomized, double-blind, multi-dose, active-and placebo controlled, multi-center, parallel group study of the analgesic effects of XXXX in adult patients with chronic low back pain
2009	Phase 3	Insomnia	A phase 2, randomized, double-blind, placebo and active comparator controlled study of the safety and efficacy of XXXX in outpatients with insomnia
2009	Phase 3	Migraine	A multicenter, randomized, double-blind, placebo-controlled, crossover trial to evaluate the efficacy and tolerability of XXXX 10mg for the treatment of acute migraine in XXXX non-responders
2009	Phase 3	Schizophenia	A 52-week, multicenter, open-label study to evaluate the effectiveness of XXXX intramuscular depot as maintenance treatment in patients with schizophrenia
2009	Phase 3	Schizophrenia	A 52-week, multicenter, randomized, double-blind, placebo-controlled study to evaluate efficacy, safety, and tolerability of an intramuscular depot formulation of XXXX (XXXX) as maintenance treatment in patients with schizophrenia
2009	Phase 3b	Major Depressive Disorder	A multi-center, double-blind, randomized, placebo-controlled study to evaluate functional outcome in outpatients with major depressive disorder treated with XXXX XXXX sustained release

2009	Phase 3b	Opioid Dependence	Open-label study of the safety and tolerability of XXXX administered to health care professionals participating in an extended outpatient treatment program for opioid dependence
2009	Phase 4	Chronic Low Back Pain	A randomized, multicenter, long term study of the safety of XXXX in patients with chronic low back pain
2008	Phase 2	Methamphetamine Dependence	XXXX for treatment of methamphetamine dependence
2008	Phase 3	Major Depressive Disorder with Psychotic Features	A double-blind, placebo-controlled study of the efficacy and safety of XXXX (XXXX) vs. placebo in the treatment of psychotic symptoms in patients with major depressive disorder with psychotic features
2008	Phase 3b	Migraine	A randomized, double-blind, placebo-controlled, parallel-group, phase 3 study of XXXX in adult migraineurs for a single migraine followed by open-label extension
2008	Phase 4	Depression	An open-label study to evaluate the prevalence of phenotypic poor metabolizers at XXXX among XXXX treated outpatients with depression
2008	Survey	Depression with Fatigue Questionnaire	Psychometric validation of the fatigue associated with depression questionnaire (FAsD)
2007	Phase 3	Bipolar I Disorder	A six week, randomized, double-blind, multicenter, fixed-flexible dose, placebo-controlled study evaluating the efficacy and safety of oral XXXX in outpatients with bipolar I disorder
2007	Phase 3	Opioid Dependence	A randomized, double-blind, placebo-controlled, multi-center study of XXXX in patients with opioid dependence
2007	Phase 3b	Chronic Low Back Pain	A six week double-blind, randomized, multicenter comparison study of the analgesic effectiveness of XXXX 200mg BID compared to XXXX XXXX 50mg QID in subjects with chronic low back pain
2007	Phase 4	Insomnia	A long-term safety and efficacy study of XXXX in elderly subjects with primary chronic insomnia
2007	Phase 4	Insomnia	Randomized, double-blind, placebo-controlled study to assess whether the administration of XXXX could facilitate the disconinuation of XXXX (XXXX) ≥mg therapy in subjects with chronic insomnia