

# **Paul E. Wylie, M.D.**

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## **Research Affiliations**

### **Offices**

#### **Preferred Research Partners, Inc.**

11219 Financial Centre Parkway, Suite 320  
Little Rock, AR 72211  
(501) 553-9987  
(501) 553-9986 FAX

#### **Preferred Research Partners Arkansas Center for Sleep Medicine**

11219 Financial Center Parkway, Suite 101  
Little Rock, AR 72211  
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The Arkansas Center for Sleep Medicine (ARCSM) is a private independently owned and operated sleep-testing facility that is not affiliated with or located within a hospital. The 3-bed sleep lab is research dedicated for the conduct of clinical trials.

## **Education**

1980-84: University of Oklahoma Norman, Oklahoma Bachelor of Science - Microbiology 1984-88: University of Oklahoma Health Sciences Center Oklahoma City, Oklahoma- Doctor of Medicine

1988-92: University of Arkansas for Medical Sciences, Little Rock, Arkansas- Psychiatry Internship and Residency

1993-95: Training in Sleep Medicine under supervision of Robert Galbraith, M.D., ABSM and Virgil Wooten, M.D., ABSM

## **Medical Licensure**

10-23-89 Arkansas N-7808

## **Current Employment**

- 10/1997 – Present: Arkansas Center for Sleep Medicine, PLLC – Little Rock, AR – President, Medical Director, Owner & Clinical Investigator for polysomnography lab
- January 2009 – Present: Preferred Research Partners, Inc.- Little Rock, AR – President, Medical Director, Clinical Investigator & co-owner

- 11/2014 – Present: Paul E. Wylie, MD, PA – Little Rock – President, Physician & owner of Child & Adolescent Psychiatric Private Practice

## **Professional Memberships**

1984-88: Oklahoma State Medical Association

1988-PR: Pulaski County Medical Society, Arkansas State Medical Association, American Medical Association

1993-PR: American Academy of Sleep Medicine

1997-PR: National Sleep Foundation, American Sleep Apnea Association, Restless Leg Syndrome Foundation, Narcolepsy Network

2004-PR: Association of Clinical Research Professionals Sleep Research Society

2012-2017: Physician sponsor of Arkansas Restless Legs Syndrome Support

2015-PR: Society of Anesthesia & Sleep Medicine

## **Honors and Awards**

1992: Sandoz Award in Recognition of Superior Academic Achievement and Contribution to Healthcare

1992: UpJohn Achievement Award for Excellence in Clinical Care and Teaching Abilities

6/94: Certified - American Board of Psychiatry and Neurology

4/95: Certified - American Board of Sleep Medicine

2010: Elected Fellow American Academy of Sleep Medicine

2014: Best of Little Rock – Teaching & Practice of Sleep Medicine

2020: Arkansas Times – Top Psychiatrist

2022: Best of Little Rock – Business Hall of Fame (9 consecutive years) – Teaching & Practice of Sleep Medicine

## **Staff Positions**

4/2016-PR: Active Medical Staff – Baptist Health – Little Rock, AR

8/1992-2017: Active Medical Staff - St. Vincent Infirmary - Little Rock, AR

10/97-PR: Paul E. Wylie, MD, PA – Little Rock, AR – President, Physician & owner of Psychiatry Private Practice

10/97-2016: Arkansas Center for Sleep Medicine, PLLC – Little Rock, AR – President, Physician & owner of Sleep Medicine Private Practice

4/1993-1997: Medical Director - St. Vincent Infirmary Sleep Disorders Center

6/97-2003: Active Medical Staff - Arkansas Heart Hospital - Little Rock, Arkansas

4/1994-2003: Consultant Staff - Baptist Health Sleep Center - Little Rock, Arkansas

8/2016-10/2021: Baptist Health – Little Rock, AR – Staff Psychiatrist

## **Publications**

- 2003: “An Evaluation of a New Automatically Adjusting Continuous Positive Airway Pressure (CPAP) Device”
- 2004: “An Evaluation of a New Bi-level Mode for the Treatment of Obstructive Sleep Apnea Hypopnea Syndrome (OSAHS)”
- 6/2006 Poster Presentation & article for APSS: “A Multi-center, Randomized, Controlled Trial of the First Automatically Titrating Bi-Level Positive Airway Pressure Device during Polysomnography”

- 2007: World Sleep Congress – “AFlex vs. CFlex: A Randomized, Blinded, Cross-Over Comparison Study”.
- 2007: APSS – “Evaluation of the BiPAP Auto M-Series with Biflex Device for the Treatment of OSA”.
- 2009: “The Treatment of Complex Central Sleep Apnea (CompCSA) Including Cheyne-Stokes Breathing (CSB), with Respiromics’ BiPAP autoSV Advanced Therapy System”.
- 2009: “Randomized Placebo-Controlled Study of the Pillar Palatal Implant System with CPAP: Clinical Report for Clinical Protocol 845”. Published in Journal of Clinical Sleep Medicine.
- 2010: “Sham controlled trial of the effect of Pillar implant on adherence to CPAP therapy in Obstructive Sleep Apnea/Hypopnea Syndrome”.
- 2011: “The Performance of Two Automatic Servo-ventilation Devices in the Treatment of Central Sleep Apnea”. Published in Sleep; 34(12):1693-1698.
- 2013: “A-Flex Versus C-Flex: A Randomized, Blinded, Cross-Over Comparison Study”.
- 2013: “Home-use Servo Ventilation Therapy in Chronic Pain Patients with Central Sleep Apnea: Initial and 3-month follow-up”.
- 2014: “Treatment of Central Sleep Apnea in Adaptive Pressure Support Servo-ventilation; Acute and Long-term Efficacy”.

## Research Projects

### Device:

- 2/2000: Respiromics Inc. - Comparison of Profile Lite Gel Mask to Gold Seal Gel Mask - Patient Preference
- 3/2000: Respiromics Inc.- Simplicity Mask and Headgear - Design Consultation and Effectiveness in Patient Care
- 9/2000: Respiromics Inc.- Simplicity Mask - Comparison of Patient Preference for Prototypes
- 1/2001: Respiromics Inc.- Comparison of Effectiveness in Treatment of Obstructive Sleep Apnea-BiPAP versus BiFLEX
- 5/2001: Respiromics Inc.- Comparison of Simplicity Deluxe Mask Prototype to Simplicity Original Mask
- 5/2001: Respiromics Inc.- Evaluation of the REMSTAR AutoPAP Performance in the Treatment of Obstructive Sleep Apnea
- 9/2001: Respiromics Inc.- Patient In-Home Comparison / Preference Study - BiPAP versus BiFlex
- 9/2001: Respiromics Inc. - Evaluation of a new device (Synchrony) for the treatment of Cheyne-Stokes respiration in patients with congestive heart failure.
- 1/2002: Respiromics Inc.- Comparison of Standard CPAP versus REMStar AutoPAP device versus RESMED AutoSet-T
- 4/2002: Respiromics Inc. – User Validation Testing of the REMstar Pro with C-Flex.

- 6/2002: Respiromics Inc.- Validation of feasibility of Average Volume Assured Pressure Support Software when Used with BiPAP Synchrony on Patients with Respiratory Insufficiency.
- 10/2002:Respiromics Inc. - Validation of feasibility of an Auto-Adjusting Bi-Level PAP device for the treatment of OSA.
- 1/2003: Respiromics Inc. – Validation of software upgrades to the Therapy Algorithm of an Auto-Adjusting REMstar CPAP device.
- 3/2004: Respiromics Inc. – Evaluation of a new device – Heart PAP – for the treatment of patients with sleep disordered breathing.
- 05/2005: Respiromics Inc. – Efficacy of an Auto-Adjusting Bi-Level PAP Device for the Treatment of OSA.
- 11/2005: Respiromics Inc. – Evaluation of the M-Series REMStar Auto C-Flex Device for the Treatment of OSA.
- 05/2006:Respiromics Inc.- Evaluation of the BIPAP Auto M-Series with Bi-flex Device for the Treatment of OSA
- 07/2006: Respiromics Inc. – The Impact of BIPAP Auto SV on OSA and Complex Sleep Apnea
- 12/2006: Respiromics Inc.- Comparison of Auto A-Flex to Auto C-flex
- 01/2007: Respiromics Inc.- Encore Anywhere User Preference Beta Test
- 01/2007: Respiromics Inc. – The Impact of BIPAP Auto SV on OSA and Complex Sleep Apnea.
- 10/2007: Respiromics Inc. – The Impact of BiPAP AutoSVTM on Central Disregulated Breathing & Chronic Pain Patients
- 10/2007: Restore Medical, Inc. – A Randomized, Placebo-Controlled Study of the Pillar Palatal Implant System with CPAP
- 01/2008: Respiromics Inc. – Stardust Screening Study
- 02/2008: Respiromics Inc. – Evaluation of a Positive Air Pressure Delivery Systems on Adherence & Outcomes (System One versus Better Together)
- 08/2008: Respiromics Inc. – Evaluation of Software Enhancements to the Respiromics BiPAP AutoSV device
- 04/2009: Respiromics Inc. – User Preference & Validation Evaluation of the New BiPAP autoSV3 device
- 07/2009: Philips Respiromics – Evaluation of the Q-Series Auto Device for the Treatment of OSA
- 10/2009: Philips Respiromics – Engineering Evaluation of the Next Generation of autoSV Devices
- 6/2010: Philips Respiromics – Evaluation of the Philips Respiromics BiPAP autoSV devices in subjects with Sleep Disorders
- 12/2010: Philips Respiromics – Philips Respiromics BiPAP autoSV4 User Preference Trial
- 8/2011: Philips Respiromics – BiPAP autoSV System One Advanced in Patients with Chronic Pain and Sleep Disordered Breathing (SDBPM-2011-01)

- 9/2011: Philips Respironics – Automated Graduated CPAP for Improved Adherence in Newly Diagnosed OSA Patients: Multicenter Trial (AR-1112-AGPAP-MS)
- 6/2012: Philips Respironics – BiPAP autoSV Advanced in Central Apnea Patients (ST-1001-ASVWO-MS)
- 7/2012: Philips Respironics – User Preference/Validation Evaluation of the New Phillips Respironics PAP Application (ST1203-APP-MS)
- 12/2012: Cereve - A Multi-center Prospective, Blinded, Randomized Crossover Study to Compare the Cereve Sleep System at Two Different Temperatures in Primary Insomnia Patients (CIP-003)
- 6/2013: Philips Respironics – Evaluation of the OmniLab 2.0 (ST-1311-OmniLab-MS)
- 6/2014: Philips Respironics – BIG4 CPAP Study (PGI-BIG4-1331-MS)
- 7/2014: Philips Respironics – Evaluation of Two Servo-Ventilation Devices (ST-1431-ASV Evaluation-ARK)
- 5/2015: Somnarus – Comparison of the Somnarus Sleep Apnea Diagnostic Technology SomnaPatch with Polysomnography (001-D)
- 7/2015: Philips Respironics – Servo-Ventilation In-Lab PSG Evaluation (ST-1517-ALE-MS)
- 7/2016: Akili Interactive Labs, Inc. - A study to assess the feasibility of and to characterize Project: EVO Monitor game-play cognitive function measurements when played daily, weekly, or multiple times per day in adults 40-55 years old (Akili-026)
- 9/2016: Philips Respironics - In-lab PSG Evaluation of Two Philips ASV Devices (ST-PHASV-16092-JP)
- 4/2017: Philips Respironics - A Double-Blind Placebo-Controlled Multi-Site Randomized Cross-Over Study of the Effectiveness and Efficacy of the PowerSleep device (AI-16128-PSPIV-LO)
- 2022: Somometrics – Sleep Apnea – SOM-029
- 2024: Alcon – Air Optix Extended Wear Contact Lenses – CLJ241-N002
- 2024: Alcon – Air Optix plus HydraGlyde Multifocal Daily/Extended Wear Contact Lenses – CLJ241-N003

**Other:**

- 2009: Development of a Sleep Measure in Restless Legs Syndrome - Pfizer
- 2014: Colorectal Cancer Biomarker Specimen Collection Study – Applied Proteomics – API-CP001
- 2014: Sequencing Study to Investigate the Underlying Genetic Cause(s) in Subjects with Restless Leg Syndrome – Xenon Pharmaceuticals, Inc.
- 2019: Guardant Health - Evaluation of ctDNA LUNAR-2 Assay in an Average Patient Screening Episode – 02-GI-002
- 2021: Janssen – Treatment Resistant Depression Market Research – 54135419DEP4008
- 2021: Idorsia – Daridorexant Primary Market Research - Insomnia

## **Pharmaceutical:**

- 1/2002: A Double-Blind, Randomized, Placebo Controlled, Parallel Group Study to Investigate the Tolerability of a Dose-Escalating Regimen of XXX in Patients Suffering from Restless Legs Syndrome.
- 2003: A Phase III, Open-Label, Fixed Dose Study to Determine the Safety of Long-Term Administration of XXX in Subjects with Chronic Insomnia.
- 2003: A Phase III, randomized, double blind, placebo-controlled outpatient study to assess the efficacy and safety of two dose levels of XXX in elderly patients with primary insomnia
- 2003: A 12-Week, Double-Blind, Placebo-Controlled, Parallel Group Study to Assess the Efficacy and Safety of XXX in Patients Suffering from Restless Leg Syndrome.
- 2003: A Phase III, Double-Blind, Outpatient, Extension Study to Assess the Long-Term Safety of Two Dose Levels of XXX in Elderly Patients with Primary Insomnia.
- 2004: A 12-month, Open-Label, Flexible-Dosage (100 to 250mg/day) Study of the Safety and Efficacy of XXX in the Treatment of Patients with Excessive Sleepiness Associated with Narcolepsy, Obstructive Sleep Apnea/Hypopnea Syndrome, or Chronic Shift Work Sleep Disorder
- 2004: A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Study to Assess the Efficacy and Safety of a Modified Release Formulation of XXX in Elderly Primary Insomnia Patients with Sleep Maintenance Difficulties
- 2005: A Double-Blind, Randomized, Placebo-Controlled, Multicenter, 30-Night Polysomnographic Study of XXX in Adult Patients with Primary Insomnia.
- 2005: A Phase III, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study to Assess the Long Term Efficacy and Safety of XXX in Primary Elderly Insomnia Patients with Sleep Maintenance Difficulties.
- 2006: A 28-day, Polysomnographic and Subjective Assessment of XXX, 10 and 30 mg, for the Treatment of Primary Insomnia: A Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Trial.
- 2006: A Long-Term Study of XXX versus Placebo Treatment Assessing Maintenance of Efficacy & Safety in Patients with Restless Legs Syndrome.
- 2006: A Phase 2, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group, Multicenter Proof-of-Concept Study to Evaluate the Safety and Efficacy of XXX Taken in Combination with XXX for the Treatment of Subjects with Chronic Insomnia
- 2006: A 12-Week, Multi-Center, Double-Blind, Placebo-Controlled, Parallel Group, Flexible Dose Polysomnography Study of XXX Controlled Release for Restless Legs Syndrome (RLS) in RLS Patients with Sleep Disturbance and Periodic Limb Movements (PLM) During Sleep.
- 2006: An Open-Label Clinical Study to Investigate Pharmacokinetics (PK) of Different Doses (0.125 mg, 0.25 mg, 0.5 mg) of XXX Administered Once Daily in Pediatric Patients who are Individually Optimized to Stable XXX Doses for the Treatment of Idiopathic Restless Legs Syndrome (RLS).
- 2007: A Randomized, Double-Blind, Placebo-Controlled, Dose-Response Study to Assess the Efficacy, Safety, and Pharmacokinetics of XXX in Patients with Restless Legs Syndrome.
- 2007: A Randomized, Double Blind, Placebo-Controlled, Parallel Group Study to Demonstrate the Subjective Treatment Effects of XXX on Sleep Using a Post Sleep Questionnaire- Interactive Voice Response System (PSQ-IVRS) in an “At-Home Setting” in an Adult Population with Chronic Insomnia.

- 2007: An Open-Label, 52-week Extension Study Assessing XXX Safety and Efficacy in Patient with Restless Legs Syndrome.
- 2007: A Randomized, Double-Blind, Placebo-Controlled, Parallel, Proof of Concept Study to Evaluate the Effectiveness of XXX to Advance the Timing of Sleep in Individuals with Delayed Sleep Phase Syndrome (DSPS).
- 2007: Efficacy and Safety of 2 mg/day of XXX on Sleep Maintenance Insomnia with a Sub-Study of the Effect of XXX on Stable Type II Diabetes Mellitus: a One Year, Mult-Center, Randomized, Double-Blind, Placebo-Controlled Study.
- 2007: A Six-Week, Double-Blind, Randomized, Placebo-Controlled, Parallel Group, Efficacy and Safety, Sleep Lab Trial with XXX in Patients with Chronic Primary Insomnia.
- 2007: A Randomized, Double-Blind, Placebo-Controlled, Dose-Response Study to Assess the Efficacy and Safety of XXX in Patients with Restless Legs Syndrome.
- 2007: Fifty-Two Weeks, Open Label Extension Trial to Evaluate Safety and Efficacy of XXX in Outpatients with Chronic Primary Insomnia who Completed the Clinical Trial Protocol 176001 or 176002.
- 2007: A Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Multicenter Outpatient Trial of XXX in Adults with Primary Insomnia.
- 2008: XXX Dose-Ranging Trial: A Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Multicenter Outpatient Trial of XXX in Adults with Nonrestorative Sleep.
- 2008: A Phase 2, Randomized, Double-Blind, Placebo-and Active-Comparator-Controlled Study of the Safety and Efficacy of XXX in Outpatients with Insomnia.
- 2009: Randomized, Double-Blind, 12-Month Study of XXX in Subjects With Restless Legs Syndrome.
- 2009: A Randomized, Double-Blind, Placebo-Controlled, 3-Way Crossover, Multicenter Polysomnography Study of Pregabalin and Pramipexole in Adults with Restless Legs Syndrome.
- 2009: Effects of Pregabalin on Sleep Maintenance in Subjects with Fibromyalgia Syndrome and Sleep Maintenance Disturbance: A Randomized, Placebo-Controlled, 2-Way Crossover, Polysomnography Study
- 2010: A Randomized, Placebo-Controlled, Double-Blind, Fixed-Dose Study of the Efficacy and Safety of Eszopiclone in Children (6 to 11 years) and Adolescents (12 to 17 years) with Attention-Deficit/Hyperactivity Disorder-Associated Insomnia.
- 2010: A Long-Term, Open-Label, Safety Study of Eszopiclone in Children (6 to 11 years) and Adolescents (12 to 17 years) with Attention-Deficit/Hyperactivity Disorder-Associated Insomnia.
- 2010: A Phase II, Randomized, Double-Blind, Placebo-Controlled Study of Nitazoxanide in Adults with Acute Uncomplicated Influenza. (Sub-Investigator)
- 2010: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Ranging, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of JNJ-27018966 in the Treatment of Patients With Irritable Bowel Syndrome With Diarrhea. (Sub-Investigator)
- 2010: A Double-Blind, Randomized, Multicenter Study of Prasugrel Compared to Placebo in Adult Patients with Sickle Cell Disease. (Sub-Investigator)
- 2010: A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Intravenous Peramivir in Subjects with Uncomplicated Influenza. The RELIEF Study. (Sub-Investigator)

- 2011: A Randomized, Double-Blind, Placebo-Controlled Study of Nitazoxanide in Adults and Adolescents with Acute Uncomplicated Influenza. (Sub-investigator)
- 2011: A Multicenter, Randomized, Double-Blind, Parallel Group, Placebo-Controlled, Phase III, Efficacy & 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: A Multicenter, Open Label, 2-Group, Dose Escalation Study of Monotherapy Administration of Rotigotine in Pediatric Subjects with Idiopathic Restless Legs Syndrome. Phase IIA
- 2011: An Open Label, Long-Term Follow-Up Study to Determine the Safety, Tolerability, & Efficacy of Rotigotine Transdermal System as Monotherapy in Pediatric Subjects with Restless Legs Syndrome. Phase IIA
- **2011: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Phase 3 Trial to Evaluate the Safety and Efficacy of Dapagliflozin in Subjects with Type 2 Diabetes with inadequately controlled hypertension on an Angiotensin-Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB) – Bristol Myers Squibb MB102073 (Sub-Investigator)**
- 2012: A Randomized, 12-Week, Double-Blind, Placebo-Controlled, Repeat Dose, Oral, Dose-Ranging Study to Assess the Safety and Efficacy of Plecanatide in Patients with Chronic Idiopathic Constipation – Synergy Pharmaceuticals – SP304-20210
- **2012: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Phase 3 Trial to Evaluate the Safety and Efficacy of Dapagliflozin in Subjects with Type 2 Diabetes with inadequately controlled hypertension treated with an Angiotensin-Converting Enzyme Inhibitor (ACEI) or Angiotensin Receptor Blocker (ARB) and an additional Antihypertensive medication - Bristol Myers Squibb MB102077 (Sub-Investigator)**
- 2012: A Multicenter, Randomized, Double-blind, Placebo-Controlled, 8-Week Study to Evaluate the Safety and Efficacy of Nebivolol and Valsartan Given as a Fixed-Dose Combination in Patients With Stage 1 or 2 Essential Hypertension – Forest Research Institute, Hypertension – NAC-MD-01
- 2012: A Phase 3 Randomized, Double-Blind, Multicenter, Placebo-Controlled, Combination Study to Evaluate the Efficacy and Safety of Lesinurad and Allopurinol Compared to Allopurinol Alone in Subjects with Gout who have had an Inadequate Hypouricemic
- Response to Standard of Care Allopurinol – Ardea Biosciences, Gout – RDEA594-301
- 2012: A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Assessing the Occurrence of Major Adverse Cardiovascular Events (MACE) in Overweight and Obese Subjects with Cardiovascular Risk Factors Receiving Naltrexone SR/Bupropion SR – Orexigen, Obesity – NB-CVOT
- 2012: A multicenter, randomized, active comparator, placebo controlled, double-blind pilot study to assess the efficacy and safety of LCQ908 alone and in combination with fenofibrate or Lovaza in patient with severe hypertriglyceridemia – Novartis, High Triglycerides – CLCQ908C2201
- 2012: A Randomized, Double Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy, Safety, and Tolerability of JNJ-27018966 in the Treatment of Patients with Diarrhea-Predominant Irritable Bowel Syndrome – Furiex Pharmaceuticals – 27018966IBS3001
- 2012: A Phase 2, Multi-Center, Randomized, Double Blind, Placebo-Controlled, Multiple-Dose Study to Determine the Safety and Efficacy of Orally Administered LX1033 in Subjects with Diarrhea-Predominant Irritable Bowel Syndrome (IBS-D) – Lexicon Pharmaceuticals – LX1033-1.201

- 2012: A 12-Week, Randomized, Double-Blind, Placebo-Controlled Study of Asimadoline in Subjects with Diarrhea-Predominant Irritable Bowel Syndrome – Tioga Pharmaceuticals – ASMP3001
- 2012: A Randomized, Double Blind, Placebo-Controlled, Parallel-Group Study of S-297995 for the Treatment of Opioid-induced Constipation (OIC) in Subjects with Non-malignant Chronic Pain Receiving Opioid Therapy – Shionogi, Inc., OIC, Phase II – 1107V9221
- 2012: A Multicenter, Randomized, Double-blinded, Placebo-controlled Study of Daikenchuto (TU100) in Subjects with Moderate Crohn's Disease – Tsumura Pharmaceuticals – TU100P2T2
- 2012: A PHASE II STUDY TO EVALUATE THE EFFICACY AND SAFETY OF 12 WEEKS OF TREATMENT WITH ORAL CNDO 201 TRICHURIS suis OVA SUSPENSION (TSO) AS COMPARED TO PLACEBO, FOLLOWED BY A 12 WEEK OPEN-LABEL TREATMENT PERIOD IN PATIENTS WITH MODERATELY TO SEVERELY ACTIVE CROHN'S DISEASE – Coronado Biosciences – CNDO-201-003
- 2012: A Phase 2b, Double-blind, Randomized, Placebo-controlled, Dose-finding Study to Evaluate Efficacy of a Novel Selective 5-HT4 Receptor Agonist, SSP-002358 Taken in Addition to a Proton Pump Inhibitor in Subjects with Gastroesophageal Reflux Disease with Persistent Regurgitation with or without Heartburn while on Proton Pump Inhibitor Therapy – Shire Pharmaceuticals – SPD557-206
- 2012: A MULTICENTER, OPEN-LABEL STUDY TO DETERMINE THE EFFECTS OF LACOSAMIDE ON SLEEP IN HEALTHY SUBJECTS - UCB, Healthy Adult, Phase I – SP1031
- 2012: A Phase 3B, Double-Blind, Randomized, Placebo-Controlled, Study of Rotigotine and its Effect on All-day Functioning and Quality of Life in Subjects with Moderate to Severe Idiopathic Restless Legs Syndrome – UCB, Restless Legs Syndrome – RL0003
- 2012: A Randomized, Double-Blind, Placebo-Controlled, Fixed-Dose, Parallel-Group Study to Compare the Efficacy, Tolerability, and Safety of 3 Doses of Gabapentin Enacarbil (GSK1838262) With Placebo in the Treatment of Subject With Moderate-to-Severe Primary Restless Legs Syndrome (RLS) – GSK/Xenopore RXP114025, Phase IV Study
- 2013: A Long-Term Extension Study of Lesinurad in Combination with Allopurinol for Subjects Completing an Efficacy & Safety Study of Lesinurad & Allopurinol – Ardea Biosciences, Gout – RDEA594-306
- 2013: A Randomized, Double-blind, Double dummy, Placebo-controlled, Parallel-group, Multicenter Study to Evaluate the Clinical Equivalence of Lubiprostone 24 mcg Capsules (Dr. Reddy's Laboratories Ltd.) With AMITIZA® (Lubiprostone) 24 mcg Capsules (Sucampo Pharmaceuticals, Inc.) in the Treatment of Chronic Idiopathic Constipation – Dr. Reddy's Laboratories, CIC – DRL-USG01-L/2012
- 2013: A Randomized, Double-Blind, Double-dummy, Placebo-controlled, Active-controlled, Parallel-group, Multicenter Trial of Oxycodone/Naloxone Controlled-release Tablets (OXN) to Assess the Analgesic Efficacy (Compared to Placebo) and the Management of Opioid-Induced Constipation (Compared to Oxycodone Controlled-release Tablets (OXY)) in Opioid-experienced Subjects with Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation who Require Around-the-clock Opioid Therapy – Purdue Pharma L.P. – ONU3705
- 2013: A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase III Study to Evaluate the Long-term Safety and Tolerability of CB-5945 for the Treatment of Opioid-induced Constipation in Adults Taking Opioid Therapy for Chronic Non-Cancer Pain – Cubist Pharmaceuticals, Inc. – 5945-SOIC-12-05
- 2013: A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase III Study to Evaluate Efficacy and Safety of CB-5945 for the Treatment of Opioid-induced Constipation in Adults Taking Opioid Therapy for Chronic Non-Cancer Pain – Cubist Pharmaceuticals, Inc. – 5945-OIC-12-04

- 2013: A Double-blind, Randomised, Placebo-controlled, Phase 3 Trial in Patients with Chronic Idiopathic Constipation to Demonstrate the Efficacy and Safety of Elobixibat 5 mg and 10 mg for 12 Weeks Followed by a 4-week Withdrawal Period – Ferring International Pharmascience Center US, Inc. – 000080
- 2013: A Multicenter, Open-label, Safety and Tolerability Extension Trial of 5 mg and 10 mg Elobixibat Daily in the Treatment of Chronic Idiopathic Constipation – Ferring International Pharmascience Center US, Inc – 000081
- 2013: An Open-Label Extension (OLE), Long-term Safety and Tolerability Study of Plecanatide in Patients with Chronic Idiopathic Constipation (CIC) – Synergy Pharmaceuticals, Inc. – SP304203-01 (CIC-OLE)
- 2013: A Randomized, Double-blind, Placebo-controlled, Parallel-group Study of Naldemedine in the Treatment of Opioid-induced Constipation in Subjects with Non-malignant Chronic Pain Receiving Opioid Therapy – Shionogi, Inc. – 1315V9232
- 2013: A 52-week, double-blind, randomised, placebo-controlled, parallel-group phase III study with re-randomisation at week 25 to evaluate the efficacy and safety of oral ibudant 10 mg once daily in female patients with irritable bowel syndrome with diarrhoea (IBS-D) – Menarini Ricerche S.p.A. – NAK-07 (IRIS-4)
- 2013: A Randomized, 12-Week, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of Plecanatide (3.0 and 6.0 mg) in Patients with Chronic Idiopathic Constipation – Synergy Pharmaceuticals, Inc. – SP304203-00 (CIC3)
- 2014: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Clinical Study to Evaluate the Efficacy and Safety of Metoclopramide Nasal Spray in Women with Symptoms Associated with Diabetic Gastroparesis – Evoke Pharma – METO-IN-003
- 2014: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Clinical Study to Evaluate the Efficacy and Safety of Metoclopramide Nasal Spray in Men with Symptoms Associated with Diabetic Gastroparesis – Evoke Pharma – METO-IN-004
- 2014: A Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Effect of Long-term Treatment with BELVIQ (lorcaserin HCl) on the Incidence of Major Adverse Cardiovascular Events and Conversion to Type 2 Diabetes Mellitus in Obese and Overweight Subjects with Cardiovascular Disease or Multiple Cardiovascular Risk – Eisai Inc. – APD356-G000-401 (CAMELLIA)
- 2014: A Phase 3, Randomized, Double Blind, Multicenter, Placebo Controlled Study to Evaluate the Efficacy and Safety of Febuxostat 40 mg XR, 80 mg XR, 40 mg IR and 80 mg IR in Subjects With Gout – Takeda Development Center Americas, Inc. – FEB-XR\_301
- 2014: A Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter, Multiregional, One Year Study to Assess the Efficacy and Safety of Twice Daily Oral Rifaximin Delayed Release Tablets for Induction of Clinical Remission with Endoscopic Response at 16 Weeks followed by Clinical and Endoscopic Remission at 52 Weeks in Subjects with Active Moderate Crohn's Disease – Salix Pharmaceuticals, Inc. – RECD3125
- 2014: A Randomized Double-Blind, Placebo Controlled, Flexible and Fixed Dose, Parallel Group Study of Extended-Release Lorazepam (EDG004) for the Treatment of Generalized Anxiety Disorder (GAD) – Edgemont Pharmaceuticals – EDG004-003
- 2014: A Randomized, Double-Blind, Placebo-Controlled, Crossover Study To Assess The Effects Of TC-6499 on Gastric Emptying Time In Diabetic Subjects with Gastroparesis – Targacept – TC-6499-12-CLP-005
- 2015: Rhythm Pharmaceuticals, Diabetic Gastroparesis – RM-131-009
- 2015: Jazz Pharmaceuticals, Narcolepsy & Excessive Daytime Sleepiness – 14-002
- 2015: Jazz Pharmaceuticals, Obstructive Sleep Apnea & Excessive Daytime Sleepiness – 14-003

- 2015: Jazz Pharmaceuticals, Long-term extension study for Obstructive Sleep Apnea or Narcolepsy with Excessive Daytime Sleepiness – 14-005
- 2015: Neurocrine Biosciences, Inc., Tardive Dyskinesia – NBI-98854-1304 (KINECT3)
- 2015: Theravance, Diabetic or Idiopathic Gastroparesis – 0099
- 2015: Synergy Pharmaceuticals, Inc., Irritable Bowel Syndrome-Constipation – SP304203-04
- 2015: Forest Research Institute, Inc., Irritable Bowel Syndrome-Constipation &/or Chronic Idiopathic Constipation – LIN-MD-10
- 2015: Janssen Research & Development, Treatment-resistant Depression – ESKETINTRD3001 (TRANSFORM-1)
- 2015: Janssen Research & Development, Treatment-resistant Depression – ESKETINTRD3003 (SUSTAIN-1)
- 2015: Neurocrine Biosciences, Inc., Tardive Dyskinesia – NBI-98854-1402 (KINECT4)
- 2015: Naurex Inc., Major Depressive Disorder – NRX1074-C-202
- 2015: Gilead, Ulcerative Colitis – GS-US-326-1100
- 2015: Sunovion Pharmaceuticals, Adult Attention Deficit Hyperactivity Disorder (ADHD) – SEP360-301
- 2016: Ferring International Pharmascience Center US, Inc., Ulcerative Colitis – 000174
- 2016: Ferring International Pharmascience Center US, Inc., Ulcerative Colitis – 000175
- 2016: Conatus Pharmaceuticals, Non-alcoholic Steatohepatitis (NASH) – IDN-6556-12
- 2016: Synergy Pharmaceuticals, Irritable Bowel Syndrome with Constipation (IBS-C) – SP304203-06
- 2016: Janssen Research & Development, Treatment-resistant Depression – ESKETINTRD3008
- 2016: Eisai Pharmaceuticals, Elderly Insomnia – E2006-G000-304
- 2016: Luitpold Pharmaceuticals, Inc., Restless Legs Syndrome – 1VIT14037
- 2016: Braintree Laboratories, Chronic Constipation – BLI400-302
- 2016: Braintree Laboratories, Opioid Induced Constipation – BLI801-203
- 2017: Takeda Pharmaceuticals – Diabetic or Idiopathic Gastroparesis – TAK906-1002
- 2017: Conatus Pharmaceuticals – Non-Alcoholic Cirrhosis – IDN-6556-17
- 2017: Shire Pharmaceuticals – Preschooler ADHD – SPD489-347
- 2017: Shire Pharmaceuticals – Preschooler ADHD – SPD489-348
- 2017: Allergan – Diabetic Gastroparesis – RLM-MD-01
- 2017: Braintree Laboratories, Bowel Prep for Colonoscopy – BLI4700-302

- 2017: Tonix Pharmaceuticals, Military-Related PTSD – TNX-CY-P301
- 2017: Vanda Pharmaceuticals, Inc. – Diabetic or Idiopathic Gastroparesis – VP-VLY-686-2301
- 2017: Allergan – Diabetic Gastroparesis – RLM-MD-04
- 2018: Freenome Holdings, Inc., Health Decisions – Colorectal Cancer Screening, FRE-001
- 2018: Allergan – Diabetic Gastroparesis – RLM-MD-03
- 2018: Tonix Pharmaceuticals, Military-Related PTSD – TNX-CY-P303
- 2018: Janssen Research & Development, Insomnia – 42847922ISM2005
- 2018: Shire Pharmaceuticals – Preschooler ADHD PK – SHP465-112
- 2018: Shire Pharmaceuticals – Adolescent ADHD – SHP465-308
- 2018: Shire Pharmaceuticals – Adolescent ADHD – SHP465-309
- 2018: AbbVie – Testosterone Replacement Therapy for Hypogonadism – M16-100
- 2018: Otsuka Pharmaceuticals – Post Traumatic Stress Disorder – 331-201-00061
- 2018: Idorsia Pharmaceuticals – Insomnia – ID-078A301
- 2018: Idorsia Pharmaceuticals – Insomnia – ID-078A303
- 2018: Janssen Research & Development – Major Depressive Disorder – 67953964MDD2001
- 2018: Neos Therapeutics – Attention Deficit Disorder in Children 4-6 y/o – NT0202.1009
- 2018: Neos Therapeutics – Attention Deficit Disorder in Children 4-6 y/o – NT0202.1010
- 2018: Tonix Pharmaceuticals - Military-Related PTSD – TNX-CY-P306
- 2018: Allergan – Diabetic Gastroparesis – 3071-305-020
- 2018: Ironwood Pharmaceuticals – GERD – C3718-302
- 2019: Tonix Pharmaceuticals - PTSD – TNX-CY-P302
- 2019: Apnimed – Obstructive Sleep Apnea – APN-002
- 2019: Aptinyx – Post-Traumatic Stress Disorder – NYX-783-2004
- 2019: Axsome Pharmaceuticals – Treatment-Resistant Depression – AXS05-301
- 2019: Biohaven Pharmaceuticals – Obsessive Compulsive Disorder – BHV4157-202
- 2019: Otsuka Pharmaceuticals – Post Traumatic Stress Disorder – 331-201-00071
- 2019: Takeda – Obstructive Sleep Apnea & Excessive Daytime Sleepiness – Phase 1 – TAK-925-2001

- 2019: LG Chem – Gout with Hyperuricemia – LG-GDCL002
- 2019: Applied Therapeutics - Diabetic Cardiomyopathy / Stage B Heart Failure at High Risk of Progression to Overt Heart Failure (Stage C Heart Failure) – AT-001-2001
- 2019: Adare Pharmaceuticals – Eosinophilic Erosive Esophagitis – SP-1011-003
- 2019: Allergan - Liver Fibrosis in Adult Subjects with Nonalcoholic Steatohepatitis – 3152-301-002
- 2019: Allergan – Constipation in Children 6-17 y/o – LIN-MD-64
- 2019: Allergan – Pediatric Participants with Functional Constipation (FC) or Irritable Bowel Syndrome with Constipation (IBS-C) – LIN-MD-66
- 2019: Allergan - Pediatric Participants (Age 2 to 5 Years) with Functional Constipation – LIN-MD-67
- 2019: Braintree Laboratories - Bowel Prep for Colonoscopy – BLI4900-302
- 2019: Phathom Pharmaceuticals – Erosive Esophagitis – EE-301
- 2019: Phathom Pharmaceuticals – H. Pylori – HP-301
- 2019: Vanda Pharmaceuticals – Diabetic or Idiopathic Gastroparesis – VP-VLY-686-3301
- 2019: Vibrant Ltd – Chronic Idiopathic Constipation – V270
- 2019: OrphoMed – Diarrhea-predominant Irritable Bowel Syndrome (IBS-D) – OM-201
- 2020: Takeda – Idiopathic Hypersomnia – Phase 1 – TAK-925-2002
- 2020: Otsuka Pharmaceuticals – ADHD in Children – Phase 1 – 405-201-00010
- 2020: Neurogastrx – Diabetic or Idiopathic Gastroparesis – NG101-201
- 2020: Guardant Health – Colorectal Cancer Screening – 02-GI-002 ECLIPSE
- 2020: Janssen – Treatment-resistant Depression – 54135419TRD4005
- 2020: Allergan – Major Depressive Disorder - 2006-308-008
- 2020: Janssen – Major Depression & Insomnia – 42847922MDD3002
- 2020: Novavax – COVID-19 Vaccine – 2019nCoV-301
- 2020: Supernus – ADHD in Preschoolers – 812P401
- 2021: Otsuka Pharmaceuticals – ADHD in Children – 405-201-00046
- 2021: Apnimed – Obstructive Sleep Apnea – APC-003
- 2021: Apnimed – Obstructive Sleep Apnea – APC-003-OLE
- 2021: Moderna – CMV Vaccine – mRNA-1647-P301

- 2021: Acerus Pharmaceuticals – Ambulatory BP monitoring in Hypogonadism – NAT-2020-01
- 2021: Purdue Pharma LP – ADHD in Preschoolers & Children – ADA4004
- 2021: Apnimed – Obstruction Sleep Apnea – APC-005
- 2021: Relmada – Major Depressive Disorder – REL-1017-302
- 2021: Relmada – Major Depressive Disorder – REL-1017-310
- 2021: AbbVie – Pediatric Migraine - 3110-305-002
- 2021: AbbVie – Pediatric Migraine – 3110-306-002
- 2021: Otsuka Pharmaceuticals – ADHD in Children & Adolescents – 405-201-00016
- 2021: Otsuka Pharmaceuticals – ADHD in Children & Adolescents – 405-201-00017
- 2021: Otsuka Pharmaceuticals – ADHD in Children & Adolescents – 405-201-00021
- 2021: Revolo Pharmaceuticals – Eosinophilic Esophagitis – RVLO 121-04
- 2021: Eliem Therapeutics – MDD in Perimenopausal Females – ETX-020155-202
- 2022: Mind Med – Generalized Anxiety Disorder – MMED008
- 2022: Merck – Treatment Resistant Depression – MK1942-006
- 2022: 89 Bio – NASH – BIO89-100-122
- 2022: Phathom Pharmaceuticals – Non-erosive Reflux Disease – NERD-301
- 2022: Alto Neurosciences – PTSD &/or MDD – ALTO-100-001
- 2022: Braintree Laboratories – Erosive Esophagitis – BLI5100-301
- 2022: Braintree Laboratories – Non-erosive Reflux Disease – BLI5100-302
- 2022: Ellodi Pharmaceuticals, L.P. – Eosinophilic Esophagitis – SP-1011-005
- 2022: Hepion Pharmaceuticals. – Non-alcoholic Steatohepatitis – HEPA-CRV431-207
- 2022: Idorsia Pharmaceuticals, Inc. – Pediatric Insomnia – ID-078A205
- 2022: Janssen – Bipolar Depression – 55308942BIP2001
- 2022: Merck – HPV Vaccine & mRNA COVID-19 Vaccine in 9-11 y/o – V503-076
- 2022: Novavax – Pediatric COVID-19 Vaccine – 2019nCoV-503
- 2022: Perception Neuroscience, Inc. – Treatment Resistant Depression – PCN-101-21
- 2022: Phathom Pharmaceuticals – Adolescents with Symptomatic GERD – VPED-102

- 2022: Supernus Pharmaceuticals – Child & Adolescent ADHD – 812P412
- 2023: Alto Neurosciences – MDD – ALTO-100-201
- 2023: AbbVie – Pediatric Episodic Migraine – M21-199
- 2023: AbbVie – Pediatric Episodic Migraine – M21-201
- 2023: Corium – Pediatric ADHD in ages 4-12 y/o – KP415.P01
- 2023: Corium – Pediatric ADHD – KP415.P02
- 2023: CinDome – Adult Diabetic Gastroparesis – CIN-102-123
- 2023: Tonix – Adult Major Depressive Disorder – TNX-TI-M201
- 2023: Tonix- Adult Chronic Migraine – TNX-OX-CM201
- 2023: Braintree Laboratories – Gastroesophageal Reflux Disease – BLI5100-303
- 2023: Phathom Pharmaceuticals – Adolescents with Symptomatic GERD – VPED-103
- 2023: Shionogi – COVID-19 & prevention in household contacts – 226T1331
- 2023: Apnimed – Sleep Apnea – APC-APN-304
- 2023: Lilly – Diabetic Peripheral Neuropathy Pain – J2P-MD-LXBD
- 2023: Supernus – Pre-schooler ADHD – 812P310
- 2023: Supernus / Navitor – Treatment Resistant Major Depressive Disorder – NAV-17A-007
- 2023: Bayer – Sleep Disturbances Associated with Menopause – 22423 (NIRVANA)
- 2023: Usona – Major Depressive Disorder – PSIL301
- 2024: Axsome – Major Depressive Disorder – SOL-MDD-301
- 2024: Axsome – Excessive Daytime Sleepiness with Shift Work Disorder – SOL-SWD-301
- 2024: Axsome – Major Depressive Disorder in Children & Adolescents – AXS-05-MDD-402
- 2024: Axsome – Major Depressive Disorder in Children & Adolescents (extension) – AXS-05-MDD-403
- 2024: AbbVie – Menstrual Migraine Prevention – M23-714
- 2024: Apnimed – Obstructive Sleep Apnea – APC-APN-305
- 2024: MindMed – Generalized Anxiety Disorder – MM120-300/301
- 2024: Apnimed – Obstructive Sleep Apnea – APC-APN-306
- 2024: Vistagen – Social Anxiety Disorder – PH94B-CL043
- 2024: Vanda – Diabetic & Idiopathic Gastroparesis – VP-VLY-686-3303
- 2024: Phathom – Eosinophilic Esophagitis – EoE-201
- 2024: Phathom – Pediatric GERD – VPED-104
- 2024: Alkermes – Narcolepsy – ALKS2680-202
- 2024: Neumora – Major Depressive Disorder – NMRA-335140-301
- 2024: Neumora – Major Depressive Disorder – NMRA-335140-501
- 2024: AbbVie – Migraine Prevention in Adults – M24-873
- 2024: Lilly – Chronic Weight Management & Obstructive Sleep Apnea – J1I-MC-GZBK/GSA2
- 2024: Alto Neuroscience – Bipolar Depression – ALTP-100-211
- 2024: VistaGen Therapeutics, Inc. - Social Anxiety Disorder (PALISADE-4) - PH94B-CL043
- 2024: Janssen (J&J) – Adjunctive Treatment for Relapse Prevention in Major Depressive Disorder (MDD) with Moderate to Severe Anhedonia – 67953964MDD3005 (VENTURA-5)
- 2024: Janssen – Adjunctive Therapy in Adult & Elderly Major Depressive Disorder (MDD) with Insomnia - 42847922MDD3003 (OARS-7)
- 2025: Cindome Pharma, Inc. - Idiopathic Gastroparesis – CIN-102-124
- 2025: Phathom Pharmaceuticals, Inc.- Eosinophilic Esophagitis (EoE) – EoE-201
- 2025: Eli Lilly & Company - Moderately to Severely Active Ulcerative Colitis – I7J-MC-DSAG
- 2025: Sanofi-Aventis - Induction study Moderately to Severely Active Ulcerative Colitis – EFC18325
- 2025: Sanofi-Aventis - Induction study Moderately to Severely Active Crohn's Disease – EFC18326

- 2025: Sanofi-Aventis - Maintenance study - Moderately to Severely Active Crohn's Disease – EFC18327
- 2025: Sanofi-Aventis - Maintenance Study - Moderately to Severely Active Ulcerative Colitis – EFC18359
- 2025: Mirador Therapeutics, Inc. - Active Crohn's Disease or Active Ulcerative Colitis (ASCEND-IBD) – MT-100-201/PROBEUC/PROBECD
- 2025: Orion Corporation - Insomnia – 3110012
- 2025: Mind Medicine, Inc. – Major Depressive Disorder (MDD) – MM123-310 (EMERGE)
- 2025: Atai Pharmaceuticals – Treatment Resistant Depression (TRD) – VLS-01-203
- 2025: AbbVie – Pediatric Chronic Migraine ages 12-17 y/o – M23-712
- 2025: Alkermes – Idiopathic Hypersomnia – ALKS2680-203
- 2025: Alkermes – Narcolepsy – ALKS2680-301
- 2025: Mineralys Therapeutics, Inc. – Moderate to Severe Sleep Apnea (OSA) – MLS-101-207
- 2025: Transcend Therapeutics – Post-Traumatic Stress Disorder (PTSD) - TSND201-PTSD-301
- 2025: Axsome Therapeutics – Fibromyalgia – AXS-14-FM-301