

## CURRICULUM VITAE

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Yardley, PA 19067

**Date of Birth:** February 22, 1962

**Place of Birth:** Philadelphia, Pennsylvania

**Education:**

1984	B.S., Nursing University of Pennsylvania
1985-1987	Post-Baccalaureate University of Pennsylvania
1991	M.D., <i>cum laude</i> Medical College of Pennsylvania

**Postdoctoral Training:**

1991-1995	Resident in Psychiatry, University of Chicago, Chicago
1995-1997	Fellowship in Schizophrenia Research, Commonwealth Research Center, Massachusetts Mental Health Center, Boston

**Licensure and Certification:**

2006	Recertification by the ABPN
1996	Certification by the American Board of Psychiatry and Neurology
1995	State of Massachusetts Medical License # 81213
1993	State of Illinois Medical License # 003-036-087746-01

**Current Position:** Vice President, Head of Neuropsychiatry Clinical Development  
2022-  
Janssen Research & Development, LLC

- Accountable for strategic leadership and oversight of all Neuropsychiatry related clinical programs and clinical development activities from Phase 2b through the end of Phase 3, as well as providing clinical oversight for relevant programs

- from lead optimization through Phase 2b.
- Responsible for cross-functional development and execution of high-quality clinical strategies and development programs, regarding design, trial conduct, oversight of safety monitoring and data analysis, in full compliance with regulatory agency requirements. Ensure appropriate data interpretation and reporting, preparation of clinical sections of key regulatory documents (e.g. IND) and Investigator Brochures.
  - Contribute to strategic direction of all Neuroscience disease areas through active participation at senior levels to determine global strategies for assets and disease areas. Actively contribute to the overall governance and strategy of the Therapeutic Area, including programs, people and budget.
  - Manage and develop staff to optimize performance. Set performance goals and monitor results, ensuring timely performance reviews and performance feedback.
  - Provide leadership to ensure resources, personnel, and expertise are appropriately prioritized and deployed to successfully pursue clinical development.
  - Provide technical and strategic expertise to ensure consistent processes, excellence in planning and delivery of clinical plans and study protocols on time and within budget. Manage the Clinical NP budget with a focus on cost-effectiveness, efficiency and maintenance of quality.

**Prior Positions:**  
2020-2022

Vice President, Compound Development Team Leader for SPRAVATO  
Janssen Research & Development, LLC

- Responsible for development and successful execution of the Global compound strategy for SPRAVATO (esketamine nasal spray), delivered through the dynamic leadership of a cross-functional Compound Development Team. Provide strategic leadership of the global development programs for Treatment Resistant Depression (TRD), Major Depression with Suicidal Ideation (MDSI), and the pediatric MDSI development program.  
Responsible for the review of scientific and medical integrity of clinical investigations, clinical and preclinical development plans, study design and conduct, study reports and all product-related publications. Primary scientific interface with internal and external partners to ensure program coordination.
- Lead cross-functional team via matrix management of individuals from project management, regulatory affairs, clinical development, strategic

marketing, market access, global medical affairs, quantitative sciences, chair of safety management, PDMS, preclinical, and other scientific and business-related disciplines. Agile leader who can adapt and manage complex situations and problem solving.

- Participate in global review, governance, and decision-making bodies within the Neuroscience Therapeutic Area at the request and direction of the Neuroscience TA head.
- Act, in concert with senior clinical personnel, as a company spokesperson in communicating clinical research findings and presentations to relevant regulatory advisory committees and review meetings, as well as to news media. Establish and maintain relationships with opinion leaders, external stakeholders, and key regulatory officials.

2013-2019

Senior Clinical Director, Neuroscience Clinical Development, Mood Disorders  
Janssen Research and Development, LLC

#### *Clinical Research*

- Served as Clinical Leader for Phase III clinical development of novel therapeutic for the treatment of patients with Major Depressive Disorder at Imminent Risk for Suicide (MDSI). Successfully led clinical proof of concept studies (Phase II) for this program, resulting in FDA Breakthrough Designation. Developed pediatric study/investigational plan. Authored protocols, briefing books, clinical study reports, manuscripts and other external communications;. Managed Advisory Panels and Data Safety Monitoring Boards; Interacted with global regulatory authorities; Organized/Managed international Investigator Meetings; Presented data to Internal/External partners; Developed and maintain relationships with external thought leaders.
- Served at Therapeutic Area and Company point person for Drug Repositioning Initiative, resulting in several collaborations with government agencies, research institutions, and academic investigators which focused on proof of concept/proof of mechanism studies of select early development pharmaceutical compounds.

#### *Team Management*

- Clinical Team Leader of MDSI program, with direct reports and matrix management responsibilities. Recruited, supervised, and mentored physicians at the Director and Senior Director level.
- Served as the Cross-functional Team Leader of group devoted to projects focusing on Disease Interception in mood disorders and launched study in youth at risk for bipolar disorder.
- Lead global neuroscience “One Team” to produce 3-day meeting with scientific and team-building content for 250 attendees.

2010-2013

Senior Clinical Director, Neuroscience External Innovation  
Janssen Research and Development, LLC

- Built relationships with academic, government, foundations, small companies and other potential partners to develop an external innovation network to create opportunities for the Neuroscience franchise. Served as expert in psychiatry R&D to provide strategic and scientific due diligence recommendations regarding external opportunities, and acted as scientific champion to shape strategy and drive deal making. Managed Neuroscience TA sponsorships. Represented Janssen in NIH-Industry initiative, “Exploring New Uses for Existing Molecules” that resulted in several collaborative translational and proof of concept studies.

2006 – 2010

Senior Clinical Director, CNS, Johnson & Johnson,  
Ortho-McNeil Janssen Scientific Affairs, LLC

*Clinical Research*

- Supervised phase IIIb/IV CNS clinical trials in schizophrenia, schizoaffective disorder, depression, anxiety and epilepsy, with oversight responsibilities including serving as medical lead for up to five concurrent trials.
- Led global registration program (sNDA) in novel indication (schizoaffective disorder) under FDA Special Protocol Assessment procedure, resulting in expedited review and US approval. CHMP approval granted after Scientific Advisory Group meeting and CHMP Oral Hearing. Multiple other country approvals granted.

*Product Development*

- Contributed to clinical strategic and tactical plans and global product positioning; Provided guidance regarding strategic decision making and resource utilization for Medical Affairs; Developed/Guided for strategies Investigator-Initiated Studies (IIS), including serving as IIS Board Member.

*Medical Support of Marketing*

- Provided medical/psychiatric review of promotional materials (guidebooks, slide kits); Cross-functional, internal training of Scientific Affairs Liaisons and Medical Services groups on new data/psychiatric topics, including development of communication tools. Launched first indication (schizophrenia) of newly approved product, second indication (bipolar mania) of a

marketed product and novel indication (schizoaffective disorder) of marketed product.

*Team Management*

- Supervised cross-functional team with up to seven direct reports. Mentored pharmaceutical physicians at the Director and Associate Director level. Managed recruitment, hiring and performance review of direct reports. Led matrix team with and without management responsibilities.

2003-2006 Clinical Director, CNS, Janssen Medical Affairs, LLC  
2002-2003 Associate Clinical Director, CNS, Janssen Medical Affairs, LLC

**Academic Appointments:**

2019- Co-Founder and Site-Director, Janssen-Drexel Fellowship in Psychiatric Drug Development  
1997-2003 Instructor in Psychiatry, Harvard Medical School  
1995-1997 Clinical Fellow in Psychiatry, Harvard Medical School  
1994-1995 Chief Resident, Department of Psychiatry, University of Chicago

**Hospital Appointments:**

2000-2002 Medical Director, Commonwealth Research and Evaluation Unit, Erich Lindemann Mental Health Center, Commonwealth Research Center  
1999-2000 Team Leader, Continuing Care Services, Massachusetts Mental Health Center  
1999-2000 Attending Clinical Psychiatrist, Day Hospital, Massachusetts Mental Health Center  
1997-2002 Attending Research Psychiatrist, Massachusetts Mental Health Center, Commonwealth Research Center

**Other Professional Positions:**

1996-2000 Consulting Psychiatrist, Quincy Hospital  
1996-2000 Consulting Psychiatrist, Milton Hospital  
1996-1999 Consulting Psychiatrist, Braintree Hospital  
1996-1999 Staff Psychiatrist, Nova Psychiatric Services  
1995-1998 Consulting Psychiatrist, HRI/Arbour Hospitals  
1994-1995 Staff Psychiatrist, Thresholds South  
1992-1994 Consulting Psychiatrist, Chicago Lakeshore Hospital  
1989 Registered Nurse, Medical College of Pennsylvania  
1984-1988 Registered Nurse (Psychiatric), The Institute of Pennsylvania Hospital  
1982-1983 Research Assistant, Children's Hospital of Philadelphia

## **Awards and Honors:**

2023	Recipient of the Johnson Medal (highest honor for innovation within J&J)
2020	Janssen Research & Development 2019 Philip B. Hoffmann Research Scientist Award
2014	Janssen Research & Development Innovation Leadership Award
2012	Janssen Research & Development Innovation Leadership Award
2009	Johnson & Johnson's Women's Leadership Initiative "J&J Women Making History"
1998	NARSAD Young Investigator Award
1996	Ethel Dupont-Warren Fellowship Award, Department of Psychiatry, Harvard Medical School
1994	Illinois Psychiatric Society Resident of the Year Award
1991	Stanley Foundation Fellowship in Psychiatry, National Alliance for the Mentally Ill (Sponsor: George M. Simpson, M.D.)
1991	The Merck Manual Award, Medical College of Pennsylvania
1991	The Paula Bernocchi Memorial Endowment Award, Medical College of Pennsylvania
1991	The AMWA Janet M. Glasgow Memorial Achievement Citation
1990	Alpha Omega Alpha Award, Medical College of Pennsylvania
1990	Alpha Omega Alpha Award, Medical College of Pennsylvania
	Stanley Foundation Fellowship in Psychiatry, National Alliance for the Mentally Ill (Sponsor: George M. Simpson, M.D.)

## **Major Committee Assignments:**

### **Volunteer**

2016-	Gala Planning Committee, American Foundation for Suicide Prevention
2015	Chairperson, United Way Annual Fund Drive, Janssen R&D
2011-2014	United Way Annual Fund Drive, Janssen R&D
2011	Co-leader, Bike Collection to benefit Trenton Boys & Girls Club
2007-2013	Board of Trustees, Springside Chestnut Hill Academy
2000-2002	Founding Board Member, Mwangaza Tanzania

### **Professional**

2020-2021	Member, National Advisory Mental Health Council (NAMHC) Workgroup on Drug Development
2013	Review Committee; National Institute of Mental Health; SBIR (MH13-100): Clinical neuroscience and entertainment software pilot partnership program to develop neuropsychiatric interventions
2000-2002	Professional Executive Committee, Erich Lindemann Mental Health Center

1998-2002 Human Studies Committee, Member, Massachusetts Mental Health Center  
 1994-1995 Council on Medical Specialty Societies, Resident Representative, American Psychiatric Association  
 1994-1995 Residency Executive Committee, Member, University of Chicago  
 1992-1995 Residency Curriculum Committee, Member, University of Chicago

**Professional Societies:**

2022- American Society of Clinical Psychopharmacology, Industry Advisory Council  
 2005- International Society for CNS Clinical Trials and Methodology, Founding Member  
     2009-2013 Membership Committee  
     2010-2012 Chair, Membership Committee  
     2011-2022 Executive Committee  
     2012-2015 Core Executive Committee and Secretary  
     2015- Scientific Program Committee  
     2015-2018 President Elect  
     2018-2020 President  
     2020-2022 Past-President  
 2007- Society of Biological Psychiatry  
 2007- Schizophrenia International Research Society  
 2002- New Jersey Psychiatric Society, Member  
 1996-2002 Massachusetts Psychiatric Society, Member  
 1993-1995 Illinois Mental Health Forum, Member  
 1992- National Alliance for the Mentally Ill, Member  
 1991- American Psychiatric Association, Member  
 1991-1995 Illinois Psychiatric Society, Member (Residents' Committee, Educational Program Committee, Governmental Affairs Committee)  
 1988-1991 Physicians for Social Responsibility, Member  
 1987-1995 American Medical Women's Association, Member

**Funded Academic Research:**

1998-2000 Lilly Center for Women's Health Grant, Awarded by Eli Lilly & Co. Hormone replacement therapy in women with schizophrenia, (Co-PI: Alan I. Green, M.D.)  
 1998-2000 National Alliance for Research in Schizophrenia and Depression Young Investigator Award: Hormone replacement therapy in women with schizophrenia, (Mentor: Alan I. Green, M.D.)  
 1997-1999 Lilly Center for Women's Health Grant, Awarded by Eli Lilly & Co. Olanzapine vs. typical neuroleptics and risperidone: Prolactin level and ovarian function (PI: Alan I. Green, M.D.)

1996-1997 Ethel Dupont Warren Award, Department of Psychiatry, Harvard Medical School Schizophrenia in women: Clinical symptoms, ovarian function, and response to neuroleptics, (Mentor: Alan I. Green, M.D.)

**Other Academic Research Experience:**

1997-2000 Massachusetts Mental Health Center, Harvard Medical School  
(Carl Salzman, M.D., Principal Investigator)  
Investigational Alzheimer's disease drug trials  
Antidepressant drug trials in elderly patients  
Prevalence and associated risk factors of psychogenic polydipsia  
Benztropine equivalence of anticholinergic medication

1995-2002 Commonwealth Research Center, Massachusetts Mental Health Center, Harvard Medical School  
(Alan I. Green, M.D., Principal Investigator)  
Clozapine response and biogenic amines in schizophrenia  
Clozapine vs. haloperidol in first episode schizophrenia  
Olanzapine vs. haloperidol in first episode schizophrenia  
Several in- and outpatient investigational antipsychotic drug trials

1994-1995 University of Chicago and Illinois State Psychiatric Institute  
(Morris B. Goldman, M.D., Principal Investigator)  
Regulation of water balance in polydipsic patients with schizophrenia  
Use of clozapine in polydipsia

1990-1991 Eastern Pennsylvania Psychiatric Institute and Haverford State Hospital, Medical College of Pennsylvania  
(Jose de Leon, M.D., Principal Investigator)

**Teaching Experience:**

**Medical School and Graduate Medical Courses**

1998-2002 Harvard Longwood Psychiatry Residency PGYII Psychopharmacology, Lecturer  
1997-2002 Psychiatry 700M.J, Lecturer and Preceptor, Harvard Medical School  
1997-2002 Psychiatry 500M.5, Attending, Harvard Medical School  
1997-2002 Psychiatry 523M.9, Preceptor, Harvard Medical School  
1994-1995 Biological Psychiatry Case Conference, Course Coordinator Department of Psychiatry, University of Chicago  
1994-1995 Introduction to Clinical Medicine: The Patient Interview, Instructor, University of Chicago, Pritzker School of Medicine  
1993-1995 Psychiatry Clerkship, Lecturer (The Mental Status Exam, The DSM-IV), University of Chicago, Pritzker School of Medicine

**Hospital Courses and Teaching Presentations**

1999 Psychopharmacology Lecture Series, Lecturer, Massachusetts Mental Health Center  
1997-1999 Psychopharmacology Extramural Training Program, Lecturer, Massachusetts Mental Health Center  
1997 Psychopharmacology Lecture Series, Lecturer, Massachusetts Mental



Health Center  
1997-2003 Intensive Diagnostic Interviewing (Board Review Course), Instructor,  
Massachusetts Mental Health Center

**Oral Presentations and Session Chair:**

- 2009 Schizoaffective disorder: Is it a valid diagnosis? Data from new treatment studies, Psychiatry Grand Rounds, University of Massachusetts, Worcester, MA
- 2009 Positive results in an era of failing trials: Population and Implementation Factors, International Society for CNS Drug Development, Las Vegas, NV
- 2009 Paliperidone ER for the Acute Treatment of Schizoaffective Disorder: A Novel Indication for Global Registration, J&J Pharma Statistics 11<sup>th</sup> Annual Meeting
- 2009 Medication satisfaction in patients with schizophrenia. International Society of Quality-of-Life Annual Meeting, New Orleans, LA
- 2010 Sex differences in depression: An industry perspective, Institute of Medicine Neuroscience Forum Workshop on Sex Differences
- 2010 Johnson & Johnson Neuroscience External Innovation, CNS Summit, Boca Raton, FL
- 2012 NOP Agonism: A Novel Mechanism for the Treatment of Anxiety, Pharmaceutical Pipeline Session NCDEU, Phoenix, AZ
- 2012 Cross Cultural Differences in the Diagnosis and Assessment of Schizoaffective Disorder, NCDEU, Phoenix, AZ
- 2012 Establishing Internal Alignment to Support External Collaborations: A Case Study from Big Pharma, 2<sup>nd</sup> Annual Drug Repositioning & Indications Discovery Conference, San Francisco, CA
- 2012 Recent Developments in NIH/Academic /Industry Collaborations, CNS Summit, Boca Raton, FL
- 2013 A Return to Rational CNS Drug Development: De-Risking Phase 3 Investments Through Rigorous Early Phase Drug Evaluations: Operational Challenges (Session Co-Chair), ISCTM, Philadelphia, PA
- 2015 ISCDD Session Chair Disease Interception, LA Vegas, NV
- 2015 ECNP drug repositioning, Amsterdam, Netherlands
- 2015 IOM panelist on drug repositioning, Washington, DC
- 2016 ISCTM – drug repositioning (speaker and session co-chair), Washington, DC
- 2016 ASCP Pharma Pipeline: PERSEVERE study results, Scottsdale, AZ
- 2016 ESSSB Round-Table: Why is it so difficult to develop “anti-suicide” drugs, Oviedo, Spain
- 2016 ACNP Hot Topics: PERSEVERE study results, Hollywood, FL
- 2017 15e Congrès de l'Encéphale, The history of esketamine, Paris, France
- 2017 SOBP Persevere: A Study of Esketamine for the Reduction of the Symptoms of Major Depressive Disorder, Including Suicidal Ideation, in Subjects Assessed to be at Imminent Risk for Suicide
- 2017 IASR/AFSP Efficacy and Safety of Intranasal Esketamine for the Rapid Reduction of Symptoms of Major Depressive Disorder, including Suicidal Ideation, in Patients Assessed to be at Imminent Risk for Suicide: A Proof-

- of-Concept Study Las Vegas, NV
- 2018 ASCP/AFSP Workshop: Inclusion of Suicidal Individuals in Treatment Trials: Insights from an Ongoing Phase 3 Drug Development Program, Miami Beach, FL
- 2018 CNS Summit, Esketamine Nasal Spray for Major Depressive Disorder with Imminent Risk for Suicide, Boca Raton FL
- 2018 Panelist, National Action Alliance for Suicide Prevention, Executive Committee Meeting, Washington, DC
- 2019 ISCTM Session Chair: Should patients with any degree of suicidal ideation or behavior be included in clinical trials? Washington, DC
- 2019 ISCTM Session Chair: Developing pharmacological treatments for the rapid reduction of suicidal ideation in depression. Copenhagen, Denmark
- 2019 ECNP New Medicines Session: Esketamine nasal spray for rapid reduction of major depressive disorder symptoms in patients at imminent risk for suicide: new data from a global registration program. Copenhagen, Denmark
- 2019 International Symposium on Suicidology and Public Health: Esketamine nasal spray for rapid reduction of major depressive disorder symptoms in patients at imminent risk for suicide. Rome, Italy
- 2019 ACNP Hot Topics: Esketamine Nasal Spray for Rapid Reduction of Depressive Symptoms in Adult Patients with MDD at Imminent Risk for Suicide: Result from the Phase 3 Program. Orlando, FL
- 2020 International Symposium on Suicidology and Public Health: New Trends in Esketamine Treatment. Rome, Italy (Virtual)
- 2020 Drexel University College of Medicine, Dept. Psychiatry Grand Rounds: Esketamine Nasal Spray in MDD: Clinical Data from Two Development Programs. Philadelphia, PA (Virtual)
- 2021 National Academies of Sciences, Engineering, and Medicine's Forum on Neuroscience and Nervous System Disorders, Workshop on Novel Molecular Targets in Mood Disorder and Psychosis: Clinical Data on the Use Case of Ketamine and Esketamine. Washington, DC (Virtual)
- 2021 Ketamine & Related Compounds International Virtual Conference 2021: Esketamine Nasal Spray: Long-term Safety
- 2021 FDA- Duke Margolis Center for Health Policy Workshop on Development and Regulation of Psychedelics for Therapeutic Use, Discussant (Virtual)
- 2021 ISCTM Session Chair: Diversity in CNS Clinical Trials (Virtual)
- 2022 ASCP Workshop: Mid-Career Workshop: How to Advance Your Career in the Hybrid/Remote Work Environment
- 2023 ASCP Panel Presentation: Designing and Implementing Studies in Patients with MDD at Imminent Risk for Suicide: Insights from a Drug Development Program, Miami FL
- 2023 CNS Summit, Janssen Neuroscience Strategy and Pipeline
- 2024 Reagan-Udall Foundation for the FDA public meeting on Advancing Psychedelic Clinical Study Design, presented "Durability of Treatment Effect: Insights from the Esketamine Nasal Spray Treatment-Resistant Depression Program"
- 2024 Session Panelist in ISCTM 20<sup>th</sup> Anniversary – Advancements & What

**Peer Reviewer:**

*American Journal of Psychiatry*  
*BMC Clinical Pharmacology*  
*Expert Opinion on Pharmacotherapy*  
*Human Psychopharmacology: Clinical and Experimental*  
*Journal of Clinical Psychiatry*  
*Journal of Clinical Psychopharmacology*  
*Neuropharmacology*  
*Primary Psychiatry*  
*Progress in Neuro-Psychopharmacology & Biological Psychiatry*  
*Psychiatry Research*  
*Psychiatry 2010*

**Bibliography:**

**Original Reports**

1. de Leon, J., Canuso, C.M., White A.O., and Simpson, G.M.: A pilot effort to determine benztropine equivalents of anticholinergic medications. *Hospital and Community Psychiatry*, 45:606-607, 1994.
2. de Leon, J., Dadvand, M., Canuso, C.M., White, A.O., Stanilla, J., and Simpson, G.M.: Schizophrenia and smoking: an epidemiological survey in a state hospital. *American Journal of Psychiatry*, 152(3):453-455, 1995.
3. de Leon, J., Dadvand, M. Canuso, C.M., White, A.O., Stanilla, J., and Simpson, G.: Polydipsia and water intoxication in a long-term psychiatric hospital. *Biological Psychiatry*, 40: 28-34, 1996.
4. Canuso, C.M. and Goldman, M.B.: The effect of neuroleptic reduction on plasma sodium in hyponatremic polydipsic schizophrenics. *Psychiatry Research*, 63: 227-229, 1996.
5. Canuso, C.M. and Goldman, M.B.: Clozapine restores water balance in schizophrenic patients with polydipsia-hyponatremia syndrome. *Journal of Neuropsychiatry and Clinical Neuroscience*, 11(1): 86-90, 1999.
6. Canuso, C.M., Hanau, M., Jhamb, K.J., and Green, A.I.: Olanzapine use in women with antipsychotic-induced hyperprolactinemia. *American Journal of Psychiatry*, 155(10): 1458, 1998.
7. Canuso, C.M., Goldstein, J.M., Wojcik, J., Dawson, R. Brandman, D., Klibanski, A., Schildkraut, J.J., Green, A.I: Antipsychotic medication, prolactin elevation, and ovarian function in women with schizophrenia and schizoaffective disorder. *Psychiatry Research*, 111: 11-20, 2002.
8. Hirschfeld, R.M.A., Keck Jr., P.E., Kramer, M, Karcher, K., Canuso, C.M., Eerdeken, M., Grossman, F.: Rapid antimanic effect of risperidone monotherapy: A 3-week

multicenter, double-blind, placebo-controlled trial. *American Journal of Psychiatry*, 161(6): 1057-1065, 2004.

9. Hirschfeld, R.M.A, Eerdekens, M, Kalali, AH, Canuso, C.M., Khan, AA, Karcher, K, Palumbo, JM: An open label extension trial of risperidone monotherapy in the treatment of bipolar I disorder. *International Clinical Psychopharmacology*, 21(1): 11-20, 2006
10. Rapaport, M.H., Gharabawi, G.M., Canuso, C.M. et al.: Effects of Risperidone Augmentation in Patients with Treatment-Resistant Depression: Results of Open-Label Treatment Followed by Double-Blind Continuation. *Neuropsychopharmacology* 1-9, 2006.
11. Alexopoulos, G.S., Canuso, C.M., Gharabawi, G.M., Bossie, C.A., Greenspan, A., Turkoz, I., Reynolds, C. A Placebo-Controlled Study of Relapse Prevention with Risperidone Augmentation in Older Patients with Resistant Depression. *American Journal of Geriatric Psychiatry*, Jan;16(1): 21-30, 2008 (On-line Publication October 10, 2007).
12. Wu, J.H.; Dickson, M.; Durkin, M.; Canuso, C.M.: Treated Liver Diseases in Medicaid Recipients with Schizophrenia or Bipolar Disorder. *Primary Psychiatry*, 14(10): 71-79, 2007.
13. Mahmoud, R.A.; Pandina, G.J.; Turkoz, I.; Kosik-Gonzalez, C.; Canuso, C.M.; Kujawa, M.J.; Gharabawi-Garibaldi, G.M.: Risperidone for Treatment-Refractory Major Depressive Disorder. *Annals of Internal Medicine*, 6 November, Volume 147(9): 593-602, 2007.
14. Pandina, G.J., Canuso, C.M., Turkoz, I., Kujawa, M., Mahmoud, R.A.: Adjunctive Risperidone in the Treatment of Generalized Anxiety Disorder: A Double-Blind, Prospective, Placebo-Controlled, Randomized Trial. *Psychopharmacology Bulletin*, 40(3):1-17, 2007.
15. Lindenmayer, J.P., Bossie, C.A., Kujawa, M., Zhu, Y., Canuso, C.M.: Dimensions of Psychosis in Patients with Bipolar Mania as Measured by the PANSS. *Psychopathology*; 41 (4):264-70, 2008.
16. Canuso, C.M., Youssef, E.A., Bossie, C.A., Turkoz, I., Schreiner, A; Simpson, G.M.: Paliperidone Extended-Release Tablets in Schizophrenia Patients Previously Treated With Risperidone *International Clinical Psychopharmacology*, 23:209-215, 2008.
17. Pandina, G., Revicki, D., Kleinman, Turkoz, I., Canuso, C., Wu, J., Mahmoud, R., Gharabawi, G.: Psychometric Evaluation of a Patient-Rated Most Troubling Symptom Scale for Generalized Anxiety Disorder Clinical Trials. *Psychopharmacol Bull*, 41(3), 68-90, 2008.
18. Canuso, C.M., Bossie, C.A., Zhu, Y., Youssef, E, Dunner, D.L.: Psychotic symptoms in patients with bipolar mania. *Journal of Affective Disorders*, 111(2-3), 164-169, 2008.

19. Turkoz, I, Bossie C.A., Dirks, B., Canuso, C.: Direct and indirect effects of paliperidone extended-release tablets on negative symptoms of schizophrenia. *Neuropsychiatric Disease and Treatment*; 4(5), 949-58, 2008.
20. Canuso, C.M., Dirks, B., Carothers, J., Kosik-Gonzalez, C., Bossie, C.A., Zhu, Y., Damaraju, C.V., Kalali, A.H., Mahmoud, R.: A randomized, double-blind, placebo-controlled study of paliperidone extended-release and quetiapine in inpatients with recently exacerbated schizophrenia. *American Journal of Psychiatry*; 166:691-701, 2009.
21. Canuso, C.M., Turkoz, I., Sheehan, J.J., Bossie, C.A.: Efficacy and safety of paliperidone extended-release in schizophrenia patients with prominent affective symptoms. *Journal of Affective Disorders*; Jun 2, 2009 [Epub ahead of print].
22. Canuso, C.M., Bossie, C.A., Turkoz, I., Alphas, L.: Paliperidone extended-release for schizophrenia: Effects on symptoms and functioning in acutely ill patients with negative symptoms. *Schizophrenia Research*; Jun 25, 2009 [Epub ahead of print].
23. Glick, I.D.; Bossie, C.A.; Alphas, L.; Canuso, C.M.: Onset and persistence of antipsychotic response in patients with schizophrenia. *Journal of Clinical Psychopharmacology*; 29(6) 542-547, 2009.
24. Canuso, C.M., Bossie, C.A.; Amatniek, J; Turkoz, I; Pandina, G; Cornblatt, B.: Paliperidone extended-release tablets in patients with recently diagnosed schizophrenia. *Early Intervention in Psychiatry*, 4: 64-78, 2010.
25. Canuso, C.M., Grinspan A., Kalali, A., Damaraju, C.V., Merriman, U., Alphas, L., Awad, A.G.: Medication satisfaction in schizophrenia: a blinded-initiation study of paliperidone ER in patients suboptimally responsive to risperidone. *International Clinical Psychopharmacology*, 25(3):155-64, 2010.
26. Vernon, M.K., Revicki D.A., Awad, A.G., Dirani, R., Panish, J., Canuso, C.M., Grinspan, A., Mannix, S., Kalali, A.H.: Psychometric evaluation of the Medication Satisfaction Questionnaire (MSQ) to assess satisfaction with antipsychotic medication among schizophrenia patients, *Schizophrenia Research*, 118(1-3):271-8, 2010.
27. Canuso, C.M., Kosik-Gonzalez, C., Sheehan, J., Mao, L., Kalali, A.H.: Frequency of schizoaffective disorder in a global patient population with psychotic disorders using the Mini-International Neuropsychiatric Interview, *Schizophrenia Research*, 118: 305-306, 2010.
28. Canuso, C.M.; Lindenmayer, J.P.; Kosik-Gonzalez, C.; Carothers, J.; Turkoz, I.; Bossie, C.A., Schooler, N A randomized, double-blind, placebo-controlled study of two dose ranges of paliperidone ER in the treatment of subjects with schizoaffective disorder, *Journal of Clinical Psychiatry*, 71 (5):587-589, 2010.
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- a randomized, controlled study comparing a flexible dose with placebo in patients treated with and without antidepressants and/or mood stabilizers. *Journal of Clinical Psychiatry*, Oct;30 (5):487-95, 2010.
30. Sheehan, J.J.; Kern-Sliwa, J.K.; Amatniek, J.C.; Grinspan, A.; Canuso, C.M. Atypical antipsychotic metabolism and excretion, *Current Drug Metabolism*, 11(6):516-25, Jul, 2010.
  31. Kozma, C.M.; Dirani, R.G.; Canuso, C.M.; Mao, L.; Predicting hospital admission and discharge with symptom or function scores in patients with schizophrenia: pooled analysis of a clinical trial extension, *Annals of General Psychiatry*; 9:24, 2010 [Epub ahead of print].
  32. Kozma, C.; Dirani, R.; Canuso, C.; Mao, L.; Change in employment status over 52 weeks in patients with schizophrenia: an observational study, *Current Medical Research & Opinion*; 27(2): 327-333, 2011.
  33. Turkoz, I.; Bossie, C.A., Lindenmayer, J.P.; Schooler, N ; Canuso, C.M.; Paliperidone ER and oral risperidone in patients with schizophrenia: A comparative database analysis, *BMC Psychiatry*, 11: 21, 2011.
  34. Canuso, CM; Turkoz, I; Fu, DJ; Bossie, CA. Role of paliperidone extended-release in treatment of schizoaffective disorder, *Neuropsychiatric Disease & Treatment* 6 667-679, 2010.
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52. Allen, M.H.; Bartko, J.J.; Lindenmayer, J.P.; Daniel, D.G.; Canuso, C.M.; Kosik-Gonzalez, C.; Adams, J.; Revicki, D.; Garibaldi, G.: Development and psychometric exploration of a Clinical Global Impressions Scale for Schizoaffective Disorder (CGI-SCA). Presented at the 49<sup>th</sup> Annual New Clinical Drug Evaluation Unit Meeting, Hollywood, Florida, June 29-July 2, 2009.
53. Vernon, M.K.; Dirani, R.; Panish, J.; Canuso, C.M.; Grinspan, A.; Damaraju, C.V.; Awad, A.G.; Kalali, A.: Psychometric evaluation of The Medication Satisfaction Questionnaire (MSQ) to assess satisfaction with antipsychotic medication among schizophrenia patients. Presented at the 49<sup>th</sup> Annual New Clinical Drug Evaluation Unit Meeting, Hollywood, Florida, June 29-July 2, 2009.
54. DeVane, C. L.; Passarell, J; Fiedler-Kelly, J.; Ludwig, E.; Martinez, L.; Canuso, C.M.: A pharmacokinetic simulation-based comparison of varying adherence rates for paliperidone ER and risperidone in patients with schizophrenia. Presented at the 22<sup>nd</sup>



Annual U.S. Psychiatric & Mental Health Congress, Las Vegas, Nevada, November 2-5, 2009.

55. Gersing, K.; Burchett, B.; Turner, N.; Canuso, C.M.: Identifying unique characteristics of schizoaffective disorder. Presented at the 22<sup>nd</sup> Annual U.S. Psychiatric & Mental Health Congress, Las Vegas, Nevada, November 2-5, 2009.
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58. Dunner, D.L., Bossie, C.A., Turkoz, I., Canuso, C.M.: Paliperidone extended-release (ER) in patients with schizoaffective disorder presenting with manic, mixed or depressive symptomatology. Presented at the 48<sup>th</sup> Annual American College of Neuropsychopharmacology Meeting, Hollywood, Florida, December 6-10, 2009.
59. Fu, D.J.; Bossie, C.A.; Turkoz, I.; Alphas, L.; Canuso, C.M.: Paliperidone ER as monotherapy or adjunctive therapy to mood stabilizers/antidepressants in subjects with schizoaffective disorder. Presented at the 2010 American Psychiatric Association Annual Meeting, New Orleans, Louisiana, May 22-26, 2010.
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61. Canuso, C., Singh, J., Fedgchin, M., Alphas, L., Lane, R., Pinter, C., Manji, H., Drevets, W.: PeRSEVERe: A Study of Esketamine for the Rapid Reduction of the Symptoms of Major Depressive Disorder, Including Suicidal Ideation, in Subjects Assessed to be at Imminent Risk for Suicide. ASCP; Scottsdale, AZ, May 30-June 3, 2016.
62. Alphas L, Fu DJ, Williamson D, Turkoz I, Canuso C, Wang Y, Joshi U, Jin D, O’Neill J, Jamieson C, Smith, K: Empirical Evaluation of Suicidal Ideation and Behavior Categories Established by the Columbia Classification Algorithm of Suicide Assessment (C-CASA). 14<sup>th</sup> Annual Scientific Meeting of the International Society for CNS Clinical Trials and Methodology (ISCTM), Washington, DC 20-22 February 2018.
63. Canuso C, Fu DJ, Ionescu DF, Lane R, Lim P, Hough D and Drevets W.: Design of Phase 3 Randomized Studies of Esketamine to Treat Major Depressive Disorder Symptoms, Including Suicidal Ideation, in Adult Patients Assessed to be at Imminent Risk for Suicide. 17<sup>th</sup> European Symposium on Suicide and Suicidal Behaviour (ESSSB).

Ghent, Belgium; Sept 5-8, 2018.

64. Alphas L, Williamson D, Turkoz I, Jamieson C, Canuso C, Fu DJ: Validation of Suicidal Ideation and Behavior Assessment Tool (SIBAT): Intra- and Inter-Rater Reliability. 17<sup>th</sup> European Symposium on Suicide and Suicidal Behaviour (ESSSB). Ghent, Belgium; Sept 5-8, 2018.
65. Pandina G, Kosik-Gonzalez C, Canuso CM.: Esketamine Nasal Spray for Rapid Reduction of Major Depressive Disorder Symptoms in Adolescents at Imminent Suicidal Risk: Rationale, Design and Progress of a Phase 2 Study. 17<sup>th</sup> European Symposium on Suicide and Suicidal Behaviour (ESSSB). Ghent, Belgium; Sept 5-8, 2018.
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67. Turkoz I, Fu DJ, Canuso C, Revicki D, Alphas L.: Suicidal Ideation and Behavior Assessment Tool (SIBAT): Psychometric Characterization of Patient-Reported Modules. International Society of CNS Clinical Trials and Methodology Autumn Conference. Marina Del Rey, CA: Oct 15-16, 2018.
68. Canuso C, Fu, DJ, Ionescu DF, Lane, R, Lim, P, Hough D, Drevets W, Manji H. ASPIRE 1 and 2: Phase 3 Randomized Studies of Esketamine Nasal Spray for the Rapid Reduction of Major Depressive Disorder Symptoms, Including Suicidal Ideation, in Adult Patients Assessed to be at Imminent Risk for Suicide. ACNP 57th Annual Meeting. Hollywood, FL. December 9-13, 2018.
69. Alphas L, Fu DJ, Williamson D, Turkoz I, Jamieson C, Canuso C.: Validation and Mapping of the Suicide Ideation and Behavior Assessment Tool (SIBAT). ACNP 57th Annual Meeting. Hollywood, FL. December 9-13, 2018.
70. Fu DJ, Canuso C, Ionescu D, Lane R, Qiu X, Lim P, Hough D, Drevets W, Manji H. Esketamine nasal spray for rapid reduction of major depressive disorder symptoms in patients at imminent risk for suicide: ASPIRE-1 study. 32nd European College of Neuropsychopharmacology (ECNP) Congress of Applied and Translational Neuroscience, Copenhagen, Denmark. Sept 7-10, 2019.
71. Ionescu D, Canuso C, Fu DJ, Lane R, Qiu X, Lim P, Hough D, Drevets W, Manji H. Esketamine nasal spray for rapid reduction of major depressive disorder symptoms in patients at imminent risk for suicide: ASPIRE-2 study. 32nd European College of Neuropsychopharmacology (ECNP) Congress of Applied and Translational Neuroscience, Copenhagen, Denmark.. Sept 7-10, 2019.
72. Nash A, Turkoz I, Fu DJ, Ionescu DF, Daly E, Canuso C. Esketamine nasal spray for rapid reduction of symptoms of major depressive disorder in adult patients at imminent

risk for suicide: A post-hoc analysis of North American subjects. ACNP 58th Annual Meeting. Orlando, FL. Poster M94. December 8-11, 2019.

73. Canuso C, Fu DJ, Ionescu DF, Lane R, Lim P, Hough D, Drevets W, Manji H. Esketamine nasal spray for rapid reduction of depressive symptoms in adult patients with major depressive disorder at imminent risk for suicide: results from the phase 3 program. ACNP 58th Annual Meeting. Orlando, FL. Poster W130. December 8-11, 2019.
74. Fu DJ, Turkoz I, Jamieson C, Revicki D, Rodriguez D, Bushnell DM, Canuso CM. Psychometric evaluation of the suicide ideation and behavior assessment tool (SIBAT) using data from two Phase 3 studies. ISCTM 16th Annual Scientific Meeting Feb 19-21, 2020, Washington, DC.
75. Rozjabek H, Fu DJ, Canuso C, Hartman H, Jamieson, C. Determining the Meaningful Change in Hopelessness Assessed with the Beck Hopelessness Scale in Patients with Major Depressive Disorder who have Active Suicidal Ideation with Intent. ISCTM 16th Annual Scientific Meeting Feb 19-21, 2020, Washington, DC.
76. Rozjabek H, Li N, Hartman H, Fu DJ, Canuso C, Jamieson, C. Assessing the Meaningful Change in Threshold (MCT) in the Quality of Life in Depression Scale (QLDS) using data from two Phase 3 studies. ISCTM 16th Annual Scientific Meeting Feb 19-21, 2020, Washington, DC.
77. Pandina G, Salvatore G, Saad ZS, Rassnick R, Canuso C, Solanki B, Drevets W. Interim Results from a Longitudinal Clinical and Biomarker Study in Offspring of Bipolar Parents: The Role of Impaired Global Functioning in Early Onset. ACNP 59<sup>th</sup> Annual Meeting. Dec 6-9, 2020, Virtual.
78. Fu DJ, Zhang Q, Shi L, Borentain S, Guo S, Mathews M, Anjo J, Nash A, O'Hara M, Canuso C. Effect of Esketamine Plus Standard of Care (SOC) vs SOC on Time to Remission of Depressive Symptoms in Patients With Major Depressive Disorder With Acute Suicidal Ideation or Behavior: Results From a Pooled Analysis of Aspire I and II. ACNP 59<sup>th</sup> Annual Meeting. Dec 6-9, 2020, Virtual.
79. Jamieson C, Fu DJ, Ionescu D, Lane R, Canuso C. The Patient Perspective: Esketamine Treatment for Major Depressive Disorder With Active Suicidal Ideation and Intent. ACNP 59<sup>th</sup> Annual Meeting. Dec 6-9, 2020, Virtual.
80. Jones RR, Freeman MP, Kornstein SG, Cooper K, Daly EJ Canuso CM, Nicholson, S. Efficacy and Safety of Esketamine Nasal Spray by Sex in Patients with Treatment-Resistant Depression: Findings from Short-term Randomized, Controlled Trials. AMWA106th Annual Meeting March 26-28, 2021, Virtual.
81. Kajs BL, Qiu X, Kosik-Gonzalez C, Fu DJ, Lane R, Canuso CM. The Effect of the Suicide Ideation and Behavior Assessment Tool (SIBAT) on Suicidality in Two Phase 3

Studies. International Society of CNS Clinical Trials & Methodology (ISCTM) Feb 15-17 2023, Washington, DC

82. Kosik-Gonzalez C, Fu DJ, Chen L, Lane R, Drevets WC, Canuso CM. Esketamine Nasal Spray versus Psychoactive Comparator for Rapid Reduction of Depressive Symptoms in Adolescents at Imminent Suicide Risk presented at the 2023 Annual Meeting of the American Psychiatric Association (APA), 20 - 24 May 2023, San Francisco, CA.
83. Kajs BL, Qiu X, Men Q, Fu DJ, Lane R, Canuso CM. Concordance Between Patient-Reported Outcomes (PROs) and Clinician-Reported Outcomes (ClinROs) for Suicidality from the Suicide Ideation and Behavior Assessment Tool (SIBAT) in Two Phase 3 Studies. American Society of Clinical Psychopharmacology (ASCP) Annual Meeting, May 30-June 2, 2023, Miami, FL.
84. DelBello M, Kosik-Gonzalez C, Fu DJ, Chen Li, Lane R, Drevets W, Moreno C, Canuso C. Efficacy and Saafety of Esketamine Nasal Spray Versus Psychoactive Control for Rapidily Reducing Depressive Symptoms in Adolescents with Major Depressive Disorder at Imminent Suicide Risk” Results of a Double-Blind Randomized Study. ACNP 63<sup>th</sup> Annual Meeting. Dec. 2023, Tampa, FL
85. Klein M, Bangerter A, Halter R, Pandina G, Boice M, Canuso C, Drevets, W. Efficacy and Safety of JNJ-42165279, a Fatty Acid Amide Hydrolase Inhibitor, in Adolescents and Adults with Autism Spectrum Disorder: A Randomized, Phase 2, Placebo-Controlled Study. ACNP 63<sup>th</sup> Annual Meeting. Dec. 2023, Tampa, FL