

Jay D. Kranzler, M.D., Ph.D.

CONTACT INFORMATION

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EDUCATION

- 1979 **B.A.** Pre-Medical Studies, Yeshiva University
Summa Cum Laude
Belkin Scholar
- 1983 **M.S., M.Phil.** Pharmacology, Yale University
- 1986 **M.D., Ph.D.** Psychiatry/Pharmacology, Yale University
Thesis Topic: "Studies in Biochemical Sex Differences in the Developing
Twelve Day-Old Rat Brain"

EARLY PROFESSIONAL CAREER

- 1975-1977 Research Assistant at Sloan Kettering Memorial Research Center studying
hematopoiesis (blood cell development) with Dr. Malcolm Moore;
- 1977-1978 Research Fellow studying subsets of immune cells in autoimmune diseases
at UCLA with Dr. Paul Terasaki;
- 1978 Academic Associate studying artificial intelligence at the IBM/Watson
Research Center;
- 1981-1986 Instructor in Psychiatry at Yale University.

EMPLOYMENT

Jay D Kranzler Consulting, LLC

June '16 - Present: *Principal*

Engagements include both Operational as well as Consulting Roles:

- **Management Support and Organizational Development**
 - Work with Sources of Capital to identify companies, programs, and/or concepts worthy of investment;
 - Work with Founders to launch, plan, finance, and staff NewCo's;
 - Create, Manage and Lead diverse teams both for consulting practice, as well as for consulting clients;
 - Currently serve at Acting Chief Operating Officer at Fortress Biotech to evolve strategy, raise money, improve productivity of search and evaluate team, and develop NewCo's.

- **Gene Therapy (GTx) Consulting**
 - Working with investors and management team to develop a business plan for a new well-funded GTx platform company with a primary focus on ocular diseases;
 - Developed a Gene Therapy strategy for major biotechnology player;
 - Advised on building CNS focused GTx programs at two companies – one focused on CNS small molecules, and the other a major GTx company;
 - Perform many opportunity assessments for companies, venture capitalists, and public company investors;
 - Provided Business Development expertise to negotiate deals regarding GTx programs – on both the sell side as well as the buy-side.

- **Hearing Loss Consulting**
 - Served as Senior Advisor to premier company using gene therapy to address relevant targets;
 - Designed scientific studies to determine potential of a small molecule to treat hearing loss;
 - Advised leading cochlear implant company to develop a strategy to leverage their market position to participate in development of pharmaceuticals for hearing loss applications;
 - Act as Strategic Advisor to small company focused on small molecules to treat hearing conditions;
 - Serve as Domain Expert Advisor reviewing opportunities in hearing loss for companies, venture capitalists, and public company investors.

- **Neuroscience Consulting**
 - Helped commercial stage, single product public biotech company build a CNS pipeline through in-licensing;
 - Act as Senior Advisor to **Fortress Biotech**, a public company, to identify and evaluate CNS opportunities;
 - Serve as Scientific Advisor to public company developing drugs for neurodegenerative diseases;
 - Serve as Domain Expert Advisor reviewing opportunities in neuroscience for companies, venture capitalists, and public company investors.

- **Management and Board Roles**
 - Chairman and Chief Executive Officer of **Urica Pharmaceuticals**, a company developing a novel drug to treat gout;
 - Board Member and Acting Chief Medical Officer of **Pastorus**, a private biotechnology company developing a product to treat Autistic Spectrum Disorder;
 - Board Member and Acting Chief Medical Officer of **Navitas**, a private biotechnology company developing a product to treat Portal Hypertension and NASH;
 - Board Member at **Avenue Therapeutics**, a public company developing CNS and rare disease therapeutics;
 - Board Member of **Immunobrain Checkpoint**, an Israel based private company developing a novel immunologic approach for treatment of neurodegenerative disease;

- Board Member at **Baergic Bio**, a private company developing a GABAergic drug for CNS disorders;
- Board Member of **Kore Therapeutics** and **OnTrack Therapeutics**, both companies focused on designing therapeutics from active molecules in plants.
- **Other Consulting Roles**
 - Co-Founder, and former Director, Acting CEO, and Acting Chief Medical Officer of **Perceptive Neuroscience**, a company focused on developing R-Ketamine treatment for refractory depression and other psychiatric disorders.
 - Negotiated key license agreement with Chiba University;
 - Raised financing from ATAI Life Sciences;
 - Former Acting CEO and Acting Chief Medical Officer.
 - Senior Advisor to **Panarea Partners**, an Investment Bank focused on Life Sciences transactions in the developing world;
 - Senior Advisor to **Fortress Biotech**, a public company, to improve business development productivity;
 - Strategic Advisor to **Athira Pharma**, a public company developing drugs for neurodegenerative diseases;
 - Scientific Advisor to **Bionaut**, a company developing nanobots for targeted drug delivery.
- **Previous Consulting, Board, and Acting Management Roles**
 - Former Acting CEO of **Regenovation, Inc**, developing a strategy for a new company focused on acellular approaches toward tissue regeneration, with an initial focus on bone and cartilage;
 - Former Advisor and Acting President for **Avraham Pharmaceuticals**, a company developing a drug for Alzheimer's disease and Mild Cognitive Impairment;
 - Former Chairman of the Board from inception of **Methylation Sciences, Inc**, a company developing an anti-depressant drug, assuming an Executive role during management transition;
 - Senior Advisor to **Griffin Securities**, a boutique Investment Bank, advising on M&A and financing transactions;
 - Entrepreneur in Residence at **Puretech Ventures and Acting CEO of Karuna Pharmaceuticals**, a life sciences focused venture capital firm, helping on early company formation.

Pfizer, Inc.

June '15 to June'16 Vice President and Global Head- External R&D Innovation – Biotherapeutics (BTx) and Strategic Investments

- Promoted to develop and implement strategy for External R&D Innovation for all of Pfizer's BTx units (i.e. those with a historical focus on large molecules, adding RareDiseases and Gene Therapy to existing coverage areas of Neuroscience and Pain). Examples of accomplishments included:
 - Neuroscience:
 - Promoted delivery of therapeutics to local circuits within the brain,

- resulting in several initiatives, including investing in local delivery of growth factors to striatum for treatment of Parkinson's disease;
- Developed strategy for employment and development of non-drug assets to support R&D goals including software, hardware, and big data analysis, leading to several deals and initiatives within the R&D units.
- Rare Diseases and Gene Therapy:
 - Implemented gene therapy strategy in identifying and evaluating external assets of interest consistent with company goals. Led the acquisition of Bamboo Therapeutics to expand capabilities and programs using AAV.
- Tasked with leadership on behalf of Worldwide Research and Development of new Pfizer Venture fund, called R&D Innovate (RDI), meant to invest in areas of strategic interest: In this role, worked with team toward the goal of deploying \$50MM per year, with 4 investments completed by end of 2015.

June '14 to June '15 *Global Head – External R&D Innovation – Pharmatherapeutics (PTx)*

- Promoted to develop and implement strategy for External R&D Innovation for all of Pfizer's PTx units (i.e. those with a primary focus on small molecules);
- Responsible for building external relationships which complemented Pfizer's internal programs, determining structure, and managing ongoing work;
- Assumed primary role in spearheading Pfizer's initial foray into new company formation under its R&D Innovate venture initiative. Conceived, founded, and acted as CEO for Ribbon Therapeutics, focused on treating sensorineural hearing loss. Developed scientific strategy and repositioned Pfizer legacy clinical assets as Ribbon's starting portfolio. Led effort to raise Series A of \$25-50MM. Pfizer ultimately chose to terminate and out-license assets;
- Contributed to design and implementation of Pfizer's Gene Therapy strategy.

April '13 to June '14 *Global Head – External R&D Innovation – Neuroscience, Pain, and Sensory Disorders*

- Responsible for expanding Pfizer's R&D reach for the Neuroscience and Neusentis (Pain and Sensory Disorders) R&D units through collaborations, licenses, acquisitions, and new venture formation;
- During the first year, four deals were announced:
 - Medgenesis for a drug/ device combination for treatment of Parkinson's Disease;
 - Akili for a therapeutic/ diagnostic video game;
 - Aniona for an improved anxiolytic; and,
 - Kissei for a clinical stage drug for gout.
- Awarded the W.E Upjohn Award for accomplishment, leadership, creativity, and teamwork for securing the Medgenesis deal – an unusual foray into an interventional drug device combination therapy for a company with a historical small molecule focus toward treating CNS disease.

Karuna Pharmaceuticals

May '12 to April '13 Acting President and Chief Executive Officer

Established business plan and raised funds to support development of new drug to treat schizophrenia. Company is now public and valued at \$3BB+.

Cypress Bioscience, Inc. (NASDAQ: CYPB), San Diego, CA (formerly IMRE Corporation Seattle, WA)

March 2011- December 2013 Chairman Emeritus

Dec 1995- Feb 2011 Chairman & Chief Executive Officer (formerly also Chief Financial Officer and Chief Scientific Officer)

“Workout” of a 15-year old publicly traded biotechnology company (IMRE). Market capitalization increased ten-fold during tenure. Accomplishments included:

- Raised over \$150 million in new funding, consolidated operations and reduced headcount, settled long-standing patent litigation and SEC prosecution actions, and built new scientific, clinical, and corporate relationships;
- Developed a medical device for Rheumatoid Arthritis through FDA approval. Negotiated major corporate deal with Fresenius AG;
- Developed new business concept of drug development in Fibromyalgia (FMS), a complex and misunderstood condition with both psychiatric and somatic components:
 - In-licensed and “repurposed” an anti-depressant, milnacipran, for treatment of FMS. Designed clinical trials and regulatory path through positive Phase III trials. FDA approval granted in February 2009;
 - Negotiated \$300 million corporate deal with Forest Laboratories for U.S. commercialization rights to milnacipran;
 - Diversified Cypress by acquiring rheumatology Dx products/platform. Built salesforce of 100 to sell milnacipran and Dx to specialists;
 - Inventor on key patents filed by the Company. Core use patent successfully defended against generic challenge;
 - Recruited world leaders in psychiatry and rheumatology for Scientific Advisory Board and Board of Directors;
 - Company and its principal profiled in Newsweek and the San Diego Union-Tribune, among other publications.
- Nominated for 2009 “Entrepreneur of the Year” award for accomplishments at Cypress;
- Sold company to Royalty Pharma in January 2011;
- Awarded 2011 Innovation Award by the International Society of CNS Drug Development for accomplishments at Cypress.

Cytel Corporation (NASDAQ: CYPB), La Jolla CA

1989-1995 *President, Chief Executive Officer, and Director*

- Recruited as CEO for startup biotechnology company focused on immunology drug development;
- Raised over \$300 million in the public and private markets. Cytel's market capitalization increased more than ten-fold during a six-year period;
- Negotiated strategic business development relationships to support technology growth and access clinical, regulatory and marketing expertise. Negotiated multiple strategic partnerships domestically and overseas (including exclusive licenses, joint ventures, equity placements, and R&D agreements);
- Initiated new R&D programs in Selectin Biology, Carbohydrate Chemistry, and Therapeutic Vaccines;
- Co-founded and spun off two companies (Glytec, and Sequel Therapeutics), and orchestrated merger and acquisition of two companies (Glycogen, and Receptor Laboratories);
- Took Cytel public in 1991 - first ever biotechnology company and first ever development stage company taken public by Goldman Sachs;
- Company and its principal profiled in The New York Times, Business Week, Inc. Magazine, and the San Diego Union-Tribune, among other publications;
- Nominated as "Entrepreneur of the Year" for accomplishments at Cytel.

McKinsey & Company, New York, NY

1985-1989 *Management Consultant*

- Started work for McKinsey as an outside consultant on strategic health care issues during graduate school. Invited to join the firm full-time as first in a pilot program to recruit hires without business training. Later attended a "Mini-MBA" program with PhD and JD non-MBA hires, designed by McKinsey and taught by Harvard and Yale Business School faculty;
- Helped establish the Pharmaceutical Industry practice, working with top pharmaceutical and technology companies in optimizing operational performance, improving organizational effectiveness, designing research and product/ market strategies, and recommending and implementing mergers and acquisitions;
- Headed Health Care recruiting effort for the firm, and designed and taught the internal Health Care training course ("Mini-MD").

Additional Entrepreneurial and Advisory Activities

- Co-founded Mood Sciences, a psychiatric services company focused on the treatment of depression using direct marketing to consumers. Sold to Mediconsult, a publicly traded company.
- Co-founded HUYA International, a biotechnology company that acquires Western rights to proprietary pharmaceutical products discovered in Greater China.
- Chosen by Kauffman Foundation for Entrepreneurship as a Kauffman Fellow Finalist (2007).
- Served on Board of Advisors to Analgesic Clinical Trials Innovation, Opportunities, and Networks (ACTION) - a Public Private Partnership between the FDA, Industry, and Academia to improve methodology in chronic pain trials.
- Served on Institute of Medicine Panel for Neuromodulation.

TEACHING AND RELATED EXPERIENCE

- Currently serve as Adjunct Professor and Entrepreneur-in-Residence at New York University Stern School of Business and at the NYU School of Medicine. Teach courses on Life Sciences Business at both Business and Medical Schools;
- Former Executive in Residence at UCSD's Rady School of Management;
- Developed and taught courses on *Biotechnology Industry: Structure and Strategy* and *Structured Decision Making for Problem Solving and Communications* to MBA students at UCSD's Rady School of Management, NYU's Stern School of Business, NYU Medical School, and NYU Polytechnical Institute. Mentor students in Independent Study and business plan competition. Authored three case studies for biotech course. Ranked by students as top instructor in school every semester;
- Mentor and Advisory Board Member at the Yale Entrepreneurial Institute;
- Founder of CNS Summit annual meeting focused on interface between life sciences and technology. Organized and ran full day technology program for 3 years;
- Chosen by Kauffman Foundation for Entrepreneurship as a Kauffman Fellow Finalist (2007);
- Developed and taught 3-day course in "Logic and Structure in Writing, Speaking, and Thinking" to multiple corporations and not-for-profit institutions;
- Designed and taught a course on "Introduction to the Health Care Industry" to consultants at McKinsey & Company;
- Conceptualized an alternative track behavioral science course for Yale medical students, taught together with a faculty member;
- Taught "Speech and Debate" and "Contemporary Literature" at summer session 2004 of Phillips Academy in Andover, MA;
- Developed materials and taught test preparation courses for SAT, GRE, MCAT, and DAT for the Stanley H. Kaplan Educational Center.

PERSONAL

- Divorced.
- Two sons: Michael, 35, a Graduate of Vanderbilt University, the University of Miami Law School and a practicing attorney; and, Jesse, 32, a graduate of Tisch School of the Arts NYU, highly regarded musician, restaurateur, and digital marketing entrepreneur;
- Served on NYU Parent’s Committee;
- Former Trustee of Francis Parker School;
- Former Member of Development Committee of the San Diego Museum of Contemporary Art;
- Private investor in technology-based companies as founding member of San Diego “Band of Angels” group;
- Served on Advisory Board of Yale Entrepreneurial Institute and on Yale President's Council for Technology Transfer;
- Serve as Advisor to NYU’s venture fund and on Board of the NYU Entrepreneurial Institute;
- Serve on Board of Prize4Life – not for profit focused on developing advances to diagnose and treat ALS.

Full Length Publications

- 1) Hofman F, Foon K, Smith D, **Kranzler J**, Cicciarelli J, Billing R.
(1981 Jun). Functional properties of subsets of T lymphocytes defined by specific antigens;44(3):476-84. *Clin Exp Immunol*.
- 2) **Kranzler J**, Jones E, MacLusky N, Sakamoto H, Naftolin F.
(1984 Sep). An exchange assay for the measurement of cell nuclear estrogen receptors in microdissected brain regions;43(3):895-8. *J Neurochem*.
- 3) Rauch L, **Kranzler J**, Selby N.
(April 1988). The many faces of discovery: a manager's guide to research. *Pharmaceutical Executive*.
- 4) **Kranzler, J**, Selby N, Taylor D, Weber F.
(March 1989). Going for the gold: rules for a new game in drug development. *Pharmaceutical Executive*.
- 5) **Kranzler J**, Gendreau J, Rao S.
(2002 Winter). The psychopharmacology of fibromyalgia: a drug development perspective;36(1):165-213. *Psychopharmacol Bull*.
- 6) Vaishnavi S, Nemeroff C, Plott S, Rao S, **Kranzler J**, Owens M.
(2004 Feb). Milnacipran: a comparative analysis of human monoamine uptake and transporter binding affinity;55(3):320-2. *Biol Psychiatry*.
- 7) Vitton O, Gendreau M, **Kranzler J**, Gendreau J, Rao S.
(2004 Oct). A double-blind placebo-controlled trial of milnacipran in the treatment of fibromyalgia;19 Suppl 1:S27-35. *Hum Psychopharmacol*.
- 8) Gendreau M, Gendreau J, **Kranzler J**, Ribeiro S, Gracely R, Williams D, Mease P, McLean S, Clauw D.
(2005 Oct). Efficacy of milnacipran in patients with fibromyalgia; 32(10):1975-85. *J Rheumatol*.
- 9) Rao S, Gendreau J, **Kranzler J**.
(2007 Fall). Understanding the fibromyalgia syndrome: 40 (4): 24-67. *Psychopharmacol. Bull*.
- 10) Marshall NS, Yee BJ, Desai AV, Buchanan PR, Wong, KKH, Crompton R, Melehan KL, Zack N, Rao SG, Gendreau RM, **Kranzler J**, Grunstein RR.
(2008). Two randomized placebo-controlled trials to evaluate the efficacy and tolerability of mirtazapine for the treatment of obstructive sleep apnea. *Sleep*, 31:824-831.

Publications (cont'd)

- 11) Meese PJ, Clauw DJ, Gendreau RM, , Rao SG, **Kranzler JD**, Chen W, Palmer RH. (2009). The efficacy and safety of milnacipran for the treatment of fibromyalgia, results of a randomized, double-blind, placebo-controlled trial. *J. Rheumatol*: 36:398-409.
- 12) Levendowski DJ, Zack N, Rao S, Wong K, Gendreau M, **Kranzler J**, Zavora T, Westbrook PR. (2009). Assessment of the test-retest reliability of laboratory polysomnography. *Sleep and Breathing*, 13:163-167.
- 13) **Kranzler, JD**, Gendreau RM. (2010). Role and rationale for the use of milnacipran in the management of fibromyalgia. *Neuropsychiatric Disease and Treatment* 6: 197-208.
- 14) Lee G, **Kranzler JD**, Ramasamy R, Gold-von-Simson G. (2018) Training scientists as future industry leaders: Teaching translational science from an industry executive's perspective. *J Trans Sci*: 4:1-4
- 15) J. M. Witkin, **Kranzler J**, Kaniecki K, Popik P, Smith JL, Hashimoto K, and Sporn J (2019) R-(-)-ketamine modifies behavioral effects of abused drugs predicting efficacy as a novel for substance abuse disorder. *Pharmacology Biochemistry and Behavior*, In press.

Authored Teaching Cases

- 1) **Kranzler, Jay**. "Cypress Bioscience, Inc. (A): Finding Fibromyalgia." (© 2005). *A description of how a company took advantage of the inherent complexity of drug development to establish a competitive position.*
- 2) **Kranzler, Jay**. "Cypress Bioscience, Inc. (B): Finding Milnacipran's Mate." (© 2005). *This case serves as the basis for a mock negotiation between four different parties with very different needs.*
- 3) **Kranzler, Jay**. "Cypress Bioscience, Inc. (C): Funding the Future." (© 2005). *This case is all about the "who, what, where, when, how, and why" of raising money for an established biotechnology company.*

Patents

Inventor on 20+ patents – issued and/or under review.