

## Terry L. Burkoth, Ph.D.

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### **Summary**

A scientist / executive with >40 years of industrial research and development experience. Areas of specialization include guiding novel technologies, including new molecular entities, drug delivery systems, devices and diagnostics to commercialization through all technical phases of development, including the government regulatory process.

### **Professional Experience**

#### **TheraJect Inc., Fremont, California**

An emerging drug delivery company with proprietary dissolvable micro-needle platform for gentle access through skin for delivery of vaccines and traditional, protein and polynucleotide drugs.

Board Member and Acting CEO 2004 – present

#### **PaceLine Consulting, Palo Alto, California**

Contract application of lengthy, diverse product development experience to program design or review including: problem-solving, idea generation, critical review or drafting of presentations, regulatory submissions and test data (non-statistical), product form & formulation, ADMET or safety study design, new molecular entity development and drug delivery. Other advisory services include general technical pre-investment due diligence for several operating or venture capital companies and contribution to several early stage companies as a Board-level Director, Scientific Advisory Board member or consultant.

Founder, Principal 2002 – present

#### **PowderChek Diagnostics Inc., Fremont, California**

PCD was an emerging diagnostic company with license to PowderJect's technology for gentle access to interstitial fluid for continuous self monitoring of glucose by diabetics. Duties involved guiding the technical program and establishing contacts with collaborators but, without success, with potential sources of venture funding.

In-house Sponsor- Mentor, Acting CEO and CTO-Chairman 2001 – 2003

#### **PowderJect Pharmaceuticals plc, Oxford, UK and Fremont, California**

PJP is a drug and vaccine delivery company using a transiently supersonic high pressure helium jet to propel dry powdered drugs of specific particle size into and through skin and mucous membranes for local or systemic therapeutic effect. Joining as a founder, responsibilities included early research on the generic delivery platform, development of products to deliver traditional and biotech drugs and presentations to the public and prospective clients as well as publications to communicate the company's technical goals and progress from before its IPO to a market cap of >£500 million. Consultation for PJP continued after leaving to start up PowderChek. PJP was acquired by Chiron Corp.

Founder, Senior VP, Science and Technology and Board Member 1996 - 2001

#### **Alza Corporation, Palo Alto, California**

Alza is the originator and world leader of controlled and sustained release therapeutic drug delivery. Over 10 years responsibility was held for supervision of groups of engineers and chemists developing oral osmotic systems, veterinary products, transdermal therapeutic systems, parenteral systems including erodible polymer depots

and osmotically-powered syringe pumps. Additional assignments included managing outside relationships with clients, collaborators and evaluating new technologies for acquisition or licensing.

Vice President, Product Development, Principle Scientist and Executive Director 1987 -1996

### **Zoecon Corporation, Palo Alto, California**

Zoecon, a Syntex spin-off was formed in 1968 to invent, develop and commercialize environmentally benign pesticides initially based upon insect hormones. The company grew through new products, expansion and acquisition to a fully integrated company of over \$100 million annual sales in major crop agrichemicals, specialty agrichemicals (including public health and livestock) as well as consumer products. Zoecon was acquired by Sandoz, the Swiss pharmaceutical and chemical conglomerate, now Novartis. Responsibilities included positions of increasing responsibility in technical and general management including: formulation, field testing, analytical and environmental chemistry, toxicology, microbiology, quality control, patent and trademarks, MIS and regulatory affairs and included remote R & D facilities and teams totalling more than 100 personnel during a period when five new molecular entities were developed into approved commercial products in projects of 6-8+ year duration and \$10-20 million budgets. Acquired products were improved and defended in this period, retaining and increasing market share.

Vice President, Development 1984 -1987

Director, Product Development 1977 -1984

Manager, Toxicology and Registration 1974 -1977

### **Syva Company, Palo Alto, California**

Syva, a start-up joint venture between Syntex and Varian, had basic research projects in photochemistry, organic superconductors and stable organic free radicals, and evolved into a vertically integrated medical diagnostic company, first applying electron spin resonance of stable free radical labels and then through the first commercialization of homogeneous enzyme mediated immunoassay techniques (EMIT).

Project Leader, Bioorganic & Clinical Chemistry 1973 -1974

Project Leader, Organic Photochemistry 1971 -1973

Senior Research Chemist 1969 -1971

### **Education**

Academic Visitor, Magdalen College, University of Oxford, UK 1996

NIH Postdoctoral Fellow, Columbia University, NYC, NY, 1968

Ph.D., chemistry, Stanford University , Palo Alto, California, 1967

A.B., chemistry major, Ripon College, Ripon, Wisconsin, 1963

### **Memberships:**

American Association for the Advancement of Science  
American Chemical Society  
Phi Lambda Upsilon  
Sigma Xi

### **Personal:**

Background: early years in Chicago, Illinois  
Birth: April 7, 1941  
Family Status: married, three children, college grads, two Ph.D.s  
Health: excellent, height: 5' 8"; weight: 165  
Interests: reading, cycling, distance running, car restoration

**References :** available upon request

**Publications and Patents:** ~30 papers and ~40 published patents

*Publications:*

1. " A Reinvestigation of the Reduction of 9-Carboethoxybicyclo[6.1.0] nona-2,4,6-triene", J.Org. Chem., 31, 4259 (1966).
2. "Cyclodecapentaene", J. Am. Chem. Soc., 89, 151 (1967) with E.E. vanTamelén.
3. "Cyclodeca-1,3,5,7,9-pentaene and *trans*-9,10-dihydronaphthalene", Ph.D. Dissertation, Stanford University, June 1967.
4. "The Cyclodecapentaene Problem", in J. Snyder ed. Non-Benzenoid Aromatics, Vol. 1, 1969, Academic Press, Inc., New York, with E.E. van Tamelen.
5. "Aldol-Type reactions of Diazoketones", Tetrahedron Letters, 5049 (1969).
6. "New Photochemical Reactions of  $\alpha$ -Diketones", Tetrahedron Letters, 145 (1970), with E. F. Ullman.
7. "The *trans*-9,10-Dihydronaphthalene Cyclodecapentaene Valence Bond Isomer System", J. Am. Chem. Soc., 93, 6120 (1971) with E.E. van Tamelen and R. H. Greeley.
8. "A Reinvestigation of the Alkylation of 5-(*p*-Hydroxyphenyl)-5-phenylhydantoin", Clin. Chim. Acta, 62, 73 (1975) With N. Buckley.
9. "Lindane Seed Treatment: A Risk / Benefit Analysis", in Lindane-Response of the Centre International d'Etudes du Lindane to EPA's preliminary Notice of Determination and Position Document 2 / 3 on Lindane, Volume II, 1984 with G.K. Kohn and J.W. Young.
10. "Osmotic Systems for Colon-Targeted Drug Delivery ", with F. Theeuwes, P. Wong and D. Fox, in Colonic Drug Absorption and Metabolism, Peter R. Bieck Ed., Marcel Dekker Inc. NY, 1993.
11. "Polyorthoesters for Drug Delivery: A Technical Review", Journal of Controlled Release, with E. Basso, P. Markland, W. Roorda, 1992.
12. "Use of the Polymeric Matrix as Internal Standard for Quantitation of In Vivo Delivery of Tetracycline HCl from Actisite<sup>®</sup> Tetracycline Fiber During Periodontal Treatment", J. Periodontal Res. with J. Litch, M. Encarnacion, S. Chen, J. Leonard 1996.
13. Sarphe, D.F., Johnson, B., Cormier, M., Burkoth, T.L., Bellhouse, B.J., "Bioavailability following transdermal powdered delivery (TPD) of radiolabeled inulin to hairless guinea pigs", J. Controlled Release, 47, 61, 1997.
14. Muddle, A.G., Longridge, D.J., Sweeney, P.A., Burkoth, T.L., Bellhouse, B.J., "Transdermal delivery of testosterone to conscious rabbits using PowderJect – a supersonic powder delivery system", Proc. Int. Symp. Control. Rel. Bioact. Mat., 24: 713, 1997.
15. Duckworth, G. M., Millward, H. R., Potter, C. D. O., Hewson, G., Burkoth, T.L., and Bellhouse, B. J., "Oral PowderJect<sup>®</sup>, a novel system for administering local anaesthetics to the oral mucosa", Br. Dent. J., 185, (10) 536, 1998.
16. Kwon, S.Y., and Burkoth, T.L., Powder Injection Effect on Transepidermal Water Loss (TEWL) and Drug Delivery, Supplement, Vo1, No.1 S103. AAPS (1998).
17. Kwon, S.Y., and Burkoth, T.L., "Transdermal Powder Injection Technology", C.E.R.I.E.S International Skin News, Issue 3: Understanding Skin Properties (1998).

18. Kwon, S.Y., and Burkoth, T.L., "Transdermal Powdered Delivery (TPD) Effect on Transepidermal Water Loss (TEWL) In Vivo and In Vitro", 12<sup>th</sup> International Symposium on Bioengineering and the Skin and Joint ISBS/DCES Poster Sessions (1998).
19. Longridge, D.J., Sweeney, P.A., Topham, S.J., Burkoth, T. L., Bellhouse, B. J., "Effects of payload per unit area on dermal PowderJect® delivery of testosterone to conscious rabbits", Proc. Int. Symp. Control. Rel. Bioact. Mat., 25: 595, 1998.
20. Longridge D.J., Sweeney P.A., Millward H., Burkoth T.L. and Bellhouse, B.J., "Effects of dome size and dose loading on oral PowderJect® delivery of testosterone to conscious beagle dogs" in Proc. Int. Symp. Cont. Rel. Bioact. Mater. Vol 25, pp 962-963, 1998.
21. Longridge, D.J., Sweeney, P.A., Burkoth, T.L., Bellhouse, B.J., "Effects of particle size and cylinder pressure on dermal PowderJect® delivery of testosterone to conscious rabbits", Proc. Int. Symp. Control. Rel. Bioact. Mat., 25: 964, 1998.
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23. Burkoth, T.L., "Transdermal and Transmucosal Powdered Drug and Vaccine Delivery", in Pam Barnacal, Ed. Innovations in Pharmaceutical Technology, Oxford, UK, 1999, in press.
24. Kwon, S.Y., Burkoth, T.L., Han, K-A., and Ahn, K-J., "Non-Invasive Glucose Monitoring using Powder Injection Technology", 5th US-Japan Symposium on Drug Delivery Systems (1999).
25. Kwon, S.Y., Prestrelski, S.J., O'Connor, B. and Burkoth, T.L., "In Vitro Evaluation of Transdermal Protein Delivery by Powder Injection", CRS (1999).
26. Kwon, S.Y., Hickey, P., Johnson, M.-J., Prestrelski, S. and Burkoth, T.L., "Transdermal Insulin Delivery by Powder Injection", 9th International Symposium on Recent Advances in Drug Delivery Systems (1999).
27. Burkoth, T.L., Budge, R., "Drug and Vaccine Delivery by High Velocity Dry Powder Injection", in Pharmatech Business Briefing: Drug Delivery, World Markets Research Centre Ltd., London (2000).
28. Burkoth, T.L., "Transdermal and transmucosal Powdered Drug and Vaccine Delivery", European Pharmaceutical Review, Russell Publishing Ltd, London UK (2000).
29. Swain, W.F. and Burkoth, T.L., "Needleless Injection Devices: The Shape Of Things To Come?", BioDrugs, Adis International Limited, New Zealand (in press 2001).
30. Kwon, S.-Y., Burkoth, T.L., Longridge, D.L., Millward, H., Bellhouse, B.J., Chapter 8: "Oral Transmucosal Powder Injection", pp 191-209, in W.R. Pfister and T. K. Ghosh Eds., Drug Delivery to the Oral Cavity: Molecule to Market, CRC Press, Inc Boca Raton,FL, (2005).

*Published Patents:*

1. U. S. Patent 3,843,447, "Photolytically Activated Coupling to Polypeptides", assigned to Syva Company, Palo Alto, California, 1974
2. U. S. Patent 3,859,333, "Novel PABA Release Compounds" assigned to Syva Company, Palo Alto, California, with E.F. Ullman, 1975
3. U. S. Patent 3,862,951, "2'-Quinoldinyl glycerol compounds" assigned to Syva Company, Palo Alto, California, E.F.Ullman, K. Gottwald, 1975
4. U. S. Patent 3,965,144, "Carbanilate compound for erythematous protection" assigned to Syva Company, Palo Alto, California, Packard; M.E., Ullman; E.F., Burkoth; T.L., 1976
5. Patent Appl. 06/738,713, "Methoprene-Containing Fruit and Vegetable Waxes as Quarantine Aids", assigned to Zoecon Corporation, Palo Alto, California, with R.E. Lucas and D.W. Ragsdale.
6. U. S. Patent 5,126,142, "Dispenser Comprising Ionophore", assigned to Alza Corporation, Palo Alto, California, with A. Ayer. A. Kucznski and J. Deters, 1992.
7. U. S. Patent 5,189,986, "Veterinary Transdermal Active Agent Delivery Device", assigned to Alza Corporation, Palo Alto, California, 1993.
8. U. S. Patent 5,200,195, "Process for Improving Dosage Form Delivery Kinetics", assigned to Alza Corporation, Palo Alto, California, with L. C. Dong, M. H. Dealy, P. S. L. Wong, J. D. Childers, B. L. Barclay, 1993.
9. U. S. Patent 5,223,266, "Long-Term Delivery Device With Early Startup", assigned to Alza Corporation, Palo Alto, California, with J. B. Eckenhoff, J. P. Carr and J. C. Wright, 1993.
10. U. S. Patent 5,227,167, "Long-Term Delivery Device Including Hydrophobic Loading Dose", assigned to Alza Corporation, Palo Alto, California, with J. P. Carr and J. B. Eckenhoff, 1993.
11. U. S. Patent 5,254,349, "Process for Lessening Irritation Caused by Drug", assigned to Alza Corporation, Palo Alto, California, with L.C. Dong, M. H. Dealey, P. S. L. Wong, J. Childers and B. L. Barclay, 1993.
12. U. S. Patent 5,266,332, "Method for Administering Anti-Parkinson Drug", assigned to Alza Corporation, Palo Alto, California, with L.C. Dong, M. H. Dealey, P. S. L. Wong, J. Childers and B. L. Barclay, 1993.
13. U. S. Patent 5,273,752, "Controlled Release Dispenser Comprising Beneficial Agent", assigned to Alza Corporation, Palo Alto, California, with A. Ayer. A. Kucznski and J. Deters, 1993.
14. U. S. Patent 5,348,746 "Method for administering drug" assigned to Alza Corporation, Palo Alto, California, with L.C. Dong, M.H. Dealey, P.S.L.Wong; J.D. Childers, B.L. Barclay, 1994.
15. U. S. Patent 5,368,863, "Long-Term Delivery Device With Early Startup", assigned to Alza Corporation, Palo Alto, California (with J. B. Eckenhoff, J. P. Carr and J. C. Wright) 1994.
16. U. S. Patent 5,246,746, "Method for Administering Drug", assigned to Alza Corporation, Palo Alto, California (with L.C. Dong, M. H. Dealey, P. S. L. Wong, J. Childers and B. L. Barclay, 1994.

17. PCT Patent Publication WO 94 07562, "Highly Controllable Pulsatile Delivery Device" Assigned To Alza Corporation, Palo Alto, California, With Davenport, J.M., Eckenhoff, J.B., Tao S.A., Wright J.C., 1994.
18. PCT Patent Publication WO 94 05354, "Fluid Driven Dispensing Device", assigned to Alza Corporation, Palo Alto, California, with Urquhart J., Gyory J.R., Magruder P.R., Ventura D.A., Albert C.F., Yum S.I., 1994.
19. U. S. Patent 5,614,211, "Oxybutynin Transdermal Device Having Decreased Delamination" assigned to Alza Corporation, Palo Alto, California, with R. Gale and R. Frame, 1997.
20. PCT Patent Publication WO 97 48485, "Method for Providing Dense Particle Compositions for Use in Transdermal Particle Delivery", assigned to PowderJect Research Limited, Oxford, UK, with D.F. Sarphie, 1997.
21. PCT Patent Publication WO 98 23228 (U. S. Patent Provis. Applic. 60/0312/471, 1996), "Directional Drug Delivery Stent and Method of Use", assigned to Alza Corporation, Palo Alto, California, with J.E.Brown and W.E.Roorda, 1998.
22. U. S. Patent 5,747,065, "Monoglyceride/lactate ester permeation enhancer for oxybutynin" assigned to Alza Corporation, Palo Alto, California, with E. S. Lee, T. Watanabe, R. M. Gale, 1998.
23. U. S. Patent 5,785,991 "Skin Permeation Enhancer Compositions comprising Glycerol Monolaurate and Lauryl Acetate" assigned to Alza Corporation, Palo Alto, California, with L.T. Taskovitch, N. Crisologo, 1998.
24. U. S. Patent 5,830,501, "Dosage form comprising hydrophilic polymer" assigned to Alza Corporation, Palo Alto, California, with L.C. Dong, M.H. Dealey, P.S.L.Wong; J.D. Childers, B.L. Barclay, 1998.
25. U. S. Patent 5,843,468 "Skin permeation enhancer compositions comprising glycerol monolaurate and lauryl acetate" assigned to Alza Corporation, Palo Alto, California (with L.T.Taskovich, R.D. Beste, R.M. Gale, E.S. Lee, R.D. Hamlin, S.I. Yum, 1998.
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27. U. S. Patent 5,897,878, "Method for Administering Steroid" assigned to Alza Corporation Palo Alto, California, with L. C. Dong, P. S-L. Wong, M. H. Dealey, J. D. Childers, B. L. Barclay, 1999.
28. U. S. Patent 5,900,250, Monoglyceride/lactate ester permeation enhancer for oxybutnin, assigned to Alza Corporation, Palo Alto, California, with E. S. Lee, T. Watanabe, R. M. Gale, 1999.
29. PCT Patent Publication WO 00/43058, A Method of Enhancing Needleless Transdermal Powdered Drug Delivery, assigned to PowderJect Research Limited, Oxford, UK, with Kwon, S.Y., 2000.
30. PCT Patent Publication WO 00/45792, Hydrogel Particle Formulations, assigned to PowderJect Research Limited, Oxford, UK, with O'Connor, B.H., Prestrelski, S.J., Muddle, A.G., Hafner, R., 2000.
31. PCT Patent Publication WO 00/53160, Delivery of Microparticle Formulations Using Needleless Syringe Device for Controlled-Release of Bioactive Compounds,

- assigned to PowderJect Research Limited, Oxford, UK, with Prestrelski, S.J., Saul, G.M., Brodbeck, K.J., 2000.
32. US Patent 6,602,678, Non or Minimally Invasive Monitoring Methods, assigned to PowderJect Research Limited, Oxford, UK, with Kwon, S.Y., 2003.
  33. US Patent App. 2003/0113827, Non-or minimally invasive monitoring methods, assigned to PowderJect Research Limited, Oxford, UK, 2003.
  34. US Patent App. 2003/0026842, Production of hard, dense particles, assigned to PowderJect Research Limited, Oxford, UK, with: Maa, Y-F and Prestrelski, S. J., 2003.
  35. US Patent App. 2002/0102625, Non- or minimally invasive monitoring methods, assigned to PowderJect Research Limited, Oxford, UK, with : Kwon, S-Y, 2002.
  36. US Patent App. 2002/0061336, Hydrogel particle formulation, assigned to PowderJect Research Limited, Oxford, UK, with: O'Connor, B. H, Maa, Y-F, Prestrelski, S. J., Muddle, A. and Hafner, R., 2002 .
  37. US Patent App. 2004/0220511 A1, Polymer Coated Device for Electrically Mediated Drug Delivery, assigned to Medluminal Systems Inc., Palo Alto, CA, with: Scott, N., Segal, J., and Shih, L-B, 2004. (EPO, 04751003.7-2305-US2004013408)
  38. US Patent 6,602,678, Non-or minimally invasive monitoring methods assigned to Chiron Corp.with Kwon, S-Y., 2003.
  39. US Patent, 6,893,664, Particle delivery techniques with Sarphie, D. F. , Muddle, A. G., Porter; L. M. , 2005.
  40. US Patent, 7,022,313, Hydrogel particle formulation, with O'Connor, B., Prestrelski; S. J., Maa; Y.-F., Muddle, A.,Hafner, R., 2006.
  41. US Patent 7,229,645, Spray freeze-dried compositions, assigned to PowderJect Vaccines Inc., Madison, WI, with: Maa, Y-F and Prestrelski, S. J., 2007.
  42. US Patent App. 2007/0270443, Methods and compositions for the treatment of viral infections, with: Went; G.; Chernoff; D.; Spence; P.; Fultz; T.