

IRWIN GRIFFITH, PhD
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SUMMARY: Ph.D. with over thirty years of experience in biotechnology developing therapeutic products and medical devices for the treatment of human disease conditions. Has held Executive positions in project and portfolio management, business development, product development and operations. Extensive background in discovery research, product development, preclinical toxicology, manufacturing, business development, financial modeling of business opportunities, product valuation, intellectual property, regulatory filings, quality documentation, and raising capital. Dual citizenship in Canada and US.

PROFESSIONAL EXPERIENCE: *IMBIOTECHNOLOGIES LTD. Edmonton, AB, CANADA (2009 – present)*
Chief Operating Officer

Medical device company developing embolotherapeutic products for the treatment of solid phase tumors and aneurisms. Founder, Member of the Board of Directors and Officer of the Corporation.

- Obtained 510(k) clearance from the FDA for the first biodegradable embolic device
- Obtained Medical Device License
- Raised more than \$5.0 MM in dilutive and non-dilutive financing
- Established and maintained an ISO 13485:2016-compliant quality system with MDSAP, serving as Management Representative
- Established and managed GMP manufacture of medical device family

VIREXX MEDICAL CORP. Edmonton, AB, CANADA (2004 – 2008)
Vice President for Drug Development

Responsible for all phases of drug development from identification of a potential product candidate through product launch in the Division of Infectious Diseases (2004 – 2007) and Division of Oncology (2007 – 2008). Member of the Executive Committee and Officer of the Corporation. Specific responsibilities included:

- Intellectual Property. Managed and Directed outside patent counsel. Managed development of worldwide patent strategies.

- Non-Clinical Toxicology. Developed toxicology programs with supporting rationales. Wrote protocols, placed and monitored studies for therapeutic and device products. Negotiated with Regulatory Agencies.
- Product Manufacture. Identified and Managed contract research and contract manufacturing organizations necessary for pilot and GMP product manufacture, including process development, process scale-up, formulation, stability, and fill/finish. Met aggressive timelines while staying within strict budget constraints. Directed QC program. Audited and qualified multiple facilities. Provided documentation for a successful Phase I trial application.
- Business Development. Identified in-licensing and out-licensing opportunities. Established competitive intelligence database. Analyzed prospective business opportunities.

**PROFESSIONAL
EXPERIENCE,
CONT.**

RATIONAL BIODEVELOPMENT, INC. Edmonton, AB, CANADA (2002 – present)
President

Private firm providing consulting services in business development, financial modeling, preclinical toxicology, product development, project management, product portfolio management, and general management for the biotechnology industry.

BIOMIRA, INC. Edmonton, AB, CANADA (1996 – 2002)

Senior Director, Business Development (2000 – 2002)

Head of Preclinical Toxicology (1997 – 2002)

Senior Director, Projects and Portfolio Management (1996 – 1999)

Directed business development efforts. Identified and pursued in-licensing and out-licensing opportunities. Established and led due diligence teams.

Established competitive intelligence database. Created discounted cash flow financial models used in portfolio management, analysis of prospective business opportunities, corporate valuation and corporate cash flow projections. Directed preclinical toxicology program. Standardized corporate project management across three facilities. Established corporate portfolio analysis and prioritized corporate programs.

IMMULOGIC PHARMACEUTICAL CORPORATION, Waltham, MA (1987-1995)

Senior Scientist/Program Management (1992-1995)

Staff Scientist III (1989-1992)

Staff Scientist II (1987-1989)

Created and managed multidisciplinary teams developing therapies for inflammatory allergic diseases. Managed three major corporate research programs. Co-authored multiple primary patent applications, responded to office actions and helped set patent strategy. Inventor on multiple patents. Managed a research laboratory with three direct reports.

HARVARD UNIVERSITY, Boston, MA (1985-1987)

Postdoctoral Fellow and Instructor

Correlated the structure/function relationships of murine class II histocompatibility molecules.

UNIVERSITY OF ALBERTA, Edmonton, Alberta, CANADA (1982-1985)

Postdoctoral Fellow

Training and research in cellular immunology investigating antigen-specific helper factors and B cell function in antibody-facilitated bone marrow chimeras.

**PROFESSIONAL
EXPERIENCE,
CONT.**

CORNELL UNIVERSITY, Ithaca, NY (1974-1982)

Graduate Student

Examined disease pathogenesis of myasthenia gravis in animal models.

EDUCATION:

Cornell University, Ithaca, NY

Ph.D., Immunology (1982)

M.S., Neurobiology and Behavior (1978)

University of California at Santa Cruz, Santa Cruz, CA

B.A., Psychobiology (1974)

MEMBERSHIPS:

BioAlberta Biotechnology Association (Board Member 1997 - 2004)

American Association for the Advancement of Science

COMMITTEES:

Canadian Institute for Health Research

Proof-of-Principle Grants Review Committee

Member (2003 – 2006)

Ad-Hoc Member (2006 – 2009)

Member (2010-2015)

CROSS

APPOINTMENT:

University of Alberta, Edmonton, AB

Adjunct Professor (2008 – 2014)

Department of Medical Microbiology and Immunology

Irwin Griffith
Addenda

ISSUED AND PROVISIONAL U.S. PATENTS:

1. Griffith, I.J. M.-c. Kuo, and M. Luqman. 1998. T cell epitopes of ryegrass pollen allergen. US 5,710,126.
2. Rogers, B.L., I.J. Griffith, and J.P. Morgenstern. 2000. Human T cell reactive feline protein (TRFP) isolated from house dust and uses therefor. US 6,025,162.
3. Gefter, M.L., R.D. Garman, J.L. Greenstein, Kuo, M.-c., Rogers, B.L., I.J. Griffith, J.P. Morgenstern and A.W. Brauer. 2000. Human T cell reactive feline protein (TRFP) isolated from house dust and uses therefor. US 6,048,962.
4. Griffith, I.J., J. Pollock, J.F. Bond, R.D. Garman, M.-c. Kuo, S.P Powers, M.A. Exley, X. Chen, and Z. Shaked. 2000. T cell peptides of the CRX III allergen. US 6,090,386
5. Griffith, I.J., J. Pollock, J.F. Bond, R.D. Garman, M.-c. Kuo, S.P Powers, M.A. Exley, X. Chen, and Z. Shaked. 2006. Allergenic proteins and peptides from Japanese cedar pollen. US 6,982,326
6. Griffith, I.J., M.-c. Kuo, and M. Luqman. 2006. T cell epitopes of ryegrass pollen allergen. US 7,112,333
7. Stewart, M.W., P.B. Tiege, and I.J. Griffith. 2008. Methods for treating vascular occlusion. US 61/031,635
8. Stewart, M.W. and I.J. Griffith. 2018. Sono-responsive embolic agents. PCT/CA2018/051092

PUBLICATIONS:

1. Norcross, N.L., I.J. Griffith and J.A. Lettieri. 1980. Measurement of acetylcholine receptor and anti-receptor antibodies by ELISA. *Muscle and Nerve*. 3:345-349.
2. Norcross, N.L. and I.J. Griffith. 1983. "The immunological basis for the pathogenesis of experimental autoimmune myasthenia gravis," in *Myasthenia Gravis: Molecular and Clinical Aspects*, A.T. Eldefrawi and E.X. Albuquerque, eds., Chapman and Hall, New York, pp. 347-389.
3. McCarthy, S.A., L.H. Francescutti, P. Gambel, I.J. Griffith, A. Semeluk, E. Diener and T.G. Wegmann. 1985. Identification of host lymphoid cells in antibody-facilitated bone marrow chimeras. *Transplant. Proc.* 17:510-514.
4. McCarthy, S.A., I.J. Griffith, P. Gambel, L.H. Francescutti and T.G. Wegmann. 1985. Characterization of host lymphoid cells in antibody-facilitated bone marrow chimeras. *Transplant.* 40:12-17.
5. McCarthy, S.A., I.J. Griffith, P. Gambel, A. Fotedar, L.H. Francescutti and T.G. Wegmann. 1987. Immunological competence of antibody facilitated bone marrow chimeras. *Transplant.* 44:97-105.
6. Griffith, I.J., E. Choi and L.H. Glimcher. 1987. A single base mutation in an I-A α -chain gene alters T cell recognition. *Proc. Natl. Acad. Sci. U.S.A.* 84:1090-1093.
7. Griffith, I.J., F.M. Carland and L.H. Glimcher. 1987. Alteration of a non-polymorphic residue in a class II E β gene eliminates an antibody-defined epitope without affecting T cell recognition. *J. Immunol.* 138:4480-4483.
9. Glimcher, L.H. and I.J. Griffith. 1987. Mutations of class II MHC molecules. *Immunology Today* 8:274-279.
10. Glimcher, L.H. and I.J. Griffith. 1987. Mutations of class II MHC molecules. *Trends in Immunology* 8:279-282.

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11. Griffith, I.J. and L.H. Glimcher. 1987. "Structural and functional analysis of murine class II molecules," in *H-2 Antigens. Genes, Molecules, Function*. C.S. David, ed., Plenum Press, New York, pp. 245-253.
12. Griffith, I.J., N. Nabavi, Z. Ghogawala, C. Chase, M. Rodriques, D.J. McKean and L.H. Glimcher. 1988. Structural mutation affecting intracellular transport and cell surface expression of murine class II molecules. *J. Exp. Med.* 167:541-555.
13. Liou, H.-C., B.S. Polla, D. Aragnol, L.D. Leserman, I.J. Griffith and L.H. Glimcher. 1988. A tissue-specific DNase I-hypersensitive site in a class II A α gene is under trans-regulatory control. *Proc. Natl. Acad. Sci. U.S.A.* 85:2738-2742.
14. Griffith, I.J., Z. Ghogawala, N. Nabavi, D.E. Golan, A. Myer, D.J. McKean and L.H. Glimcher. 1988. The cytoplasmic domain affects membrane expression and function of an Ia molecule. *Proc. Natl. Acad. Sci. U.S.A.* 85:4847-4851.
15. Nabavi, N., Z. Ghogawala, A. Myer, I.J. Griffith, W.F. Wade, Z.Z. Chen, D.J. McKean and L.H. Glimcher. 1989. Antigen presentation abrogated in cells expressing truncated Ia molecules. *J. Immunol.* 142:1444-1447
16. Ghogawala, Z., E. Choi, K.R. Daly, L.R. Blanco, I.J. Griffith and L.H. Glimcher. 1989. An intronic 10 base-pair deletion in a class II A β gene affects RNA processing. *Molec. and Cell. Biol.* 9:4402-4408.
17. Brown, M.A., I.J. Griffith and L.H. Glimcher. 1990. Functional and molecular characterization of I-Ag^k mutants is consistent with the predicted three dimensional structure of class II MHC molecule. *Molec. Immunol.* 27:645-660.
18. Rafnar, T., I.J. Griffith, M. Kuo, J.F. Bond, B.L. Rogers and D.G. Klapper. 1991. Cloning of *Amb a I* (Antigen E), the major allergen family of short ragweed pollen. *J. Biol. Chem.* 266:1229-1236.
19. Griffith, I.J., P.M. Smith, J. Pollock, P. Theerakulpisut, A. Avjioglu, S. Davies, T. Hough, M.B. Singh, R.J. Simpson, L.D. Ward and R.B. Knox. 1991. Cloning and sequencing of *Lol p I*, the major allergenic protein of rye-grass pollen. *FEBS Letters.* 279:210-215.
20. Morgenstern, J.P., I.J. Griffith, A.W. Brauer, B.L. Rogers, J.F. Bond, M.D. Chapman and M.-c. Kuo. 1991. Amino acid sequence of *Fel d I*, the major allergen of the domestic cat: protein sequence analysis and cDNA cloning. *Proc. Natl. Acad. Sci. U.S.A.* 88:9690-9694.
21. Rogers, B.L., C. Counsell, T.P. King, J.P. Morgenstern, I.J. Griffith and M.-c. Kuo. 1991. Complete sequence of the allergen *Amb a II*: recombinant expression and reactivity with T cells from ragweed allergic patients. *J. Immunol.* 147:2547-2552.
22. Griffith, I.J., J. Pollock, B.L. Rogers, D. Klapper and A.K. Nault. 1991. Sequence polymorphism of *Amb a I* and *Amb a II*, the major allergens in short ragweed. *Int. Arch. Allergy Appl. Immunol.* 96:296-304.
23. Griffith, I.J., S. Craig, J. Pollock, X.-B. Yu, J.P. Morgenstern and B.L. Rogers. 1992. Expression and genomic structure of the genes encoding *Fel d I*, the major allergen of the domestic cat. *Gene* 113:263-268.
24. Griffith, I.J., S. Craig, J. Pollock, X.-B. Yu, J. Morgenstern and B.L. Rogers. 1993. "Genomic organization and expression in cat tissues of the genes encoding *Fel d I*, the major allergen of the domestic cat," in *Molecular Biology and Immunology of Allergens*, Kraft, D. and A.H. Sehon, eds., CRC Press, London, pp. 255-258.
25. Kuo, M.-c., X.-j. Zhu, R. Kuory, I.J. Griffith, D. G. Klapper, J.F. Bond and B.L. Rogers. 1993. Purification and immunochemical characterization of recombinant and native ragweed allergen *Amb a II*. *Mol. Immunol.* 30:1077-1087.
26. Rogers, B.L., J. Pollock and I.J. Griffith. 1993. Complete sequence for a proteinase inhibitor cystatin homologue from the pollen of *Ambrosia artemisiifolia* (short ragweed) *Gene.* 133:219-221.

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27. Ong, E.K., M.B. Singh, I.J. Griffith and R.B. Knox. 1993. Cloning of a cDNA encoding a Group V (Group IX) isoform from rye-grass pollen that demonstrates specific antigenic immunoreactivity. *Gene*. 134:235-240.
28. Griffith, I.J., A. Lussier, R. Garman, R. Koury, H. Yeung and J. Pollock. 1993. cDNA cloning of *Cry j I*, the major allergen of *Cryptomeria japonica* (Japanese cedar). *J. Allergy Clin. Immunol.* 91:339. (Abstract)
29. Segal, D.B., T. Lam, K.A. Theriault, J. Pollock, P.V. Patev, I.J. Griffith, H. Yeung and J.F. Bond. 1993. Human IgE reactivity to purified recombinant and native grass allergens. *Eur. J. Allergy Clin. Immunol.* 48:128. (Abstract)
30. Exley, M.E., B.L. Rogers and I. J. Griffith. 1997. "The use of peptides for allergy immunotherapy", in *Allergic Mechanisms and Immunotherapeutic Strategies*, Roberts, A.M. and M.R. Walker, eds., John Wiley and Sons, London, pp. 151-176.
31. Rogers, B.L., J.F. Bond, J.P., Morgenstern, C. Counsell and I.J. Griffith. 1996. "Immunological characterization of the major ragweed allergens *Amb a I* and *Amb a II*," in *Pollen Biotechnology: Gene Expression and Allergen Characterization*, Mohapatra, S.S. and R.B. Knox, eds., Chapman and Hall, New York, pp. 211-234.
32. Smith, P.M., C. Suphioglu, I.J. Griffith, K. Theriault, R.B. Knox, and M.B. Singh. 1996. Cloning and expression in yeast *Pichia pastoris* of a biologically active form of *Cyn d I*, the major allergen of Bermuda grass pollen. *J. Allergy Clin. Immunol.* 98:331-343.
33. C.M. Richman, DeNardo, S.J., R.T. O'Donnell, D.S. Goldstein, S. Shen, D.L. Kukis, L.A. Kroger, A. Yuan, G. Boniface, I. Griffith, and G.L. DeNardo. 1999. Dosimetry based therapy in metastatic breast cancer patients using 90Y monoclonal antibody 170H.82 with autologous stem cell support and cyclosporin A. *Clin. Cancer Res.* 5(Suppl 10):3243s-3248s.
34. O'Donnell, R.T., S.J. DeNardo, A. Yuan, S. Shen, C.M. Richman, P.N. Lara, I.J. Griffith, D.S. Goldstein, D.L. Kukis, G.S. Martinez, G.R. Mirick, D.L. DeNardo, and F.J. Meyers. 2001. Radioimmunotherapy with ¹¹¹In/⁹⁰Y-2it-bad-m170 for metastatic prostate cancer; A Phase I/II study. *Clin. Cancer Res.* 7:1561-1568.
35. Owen, R.J., P.N. Nation, R. Polakowski, J.A. Biliske, P.B. Tiege and I.J. Griffith. 2012. A preclinical study of the safety and efficacy of Occlusin™ 500 Artificial Embolization Device in sheep. *Cardiovasc. Intervent. Radiol.* 35:636-644. e-published 6 Jul 2011.