

## **ATUL VARADHACHARY, M.D., PH.D.**

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### **OVERVIEW**

Successful Healthcare and Life Sciences professional. Combine strong technical knowledge and leadership in the healthcare, biotechnology and pharmaceutical spaces with strategic and operational success. Demonstrated ability to innovate, execute, and implement change in complex environments. Experience serving both innovative entrepreneurial organizations and large complex corporations in private and public settings.

### **PROFESSIONAL EXPERIENCE AND APPOINTMENTS**

#### **Since 2013: Fannin Innovation Studio**

Managing Partner.

Established in 2005, Fannin (formerly AlphaDev) is Houston's leading early-stage life science development group commercializing innovative technology in collaboration with researchers and clinicians in Houston's Texas Medical Center. We develop internally developed assets as well as those in-licensed in from academic institutions with the goal of advancing them through clinical proof-of-concept. We have a dozen technologies in active development, split between therapeutics and medical devices.

#### **2011 - 2013: Reliance Life Sciences**

President, U.S. Operations, Reliance Life Sciences (RLS) and RLS, Inc.

Reliance Life Sciences is one of India's leading integrated Life Sciences companies with a leadership position in multiple spaces, including biosimilars, plasma proteins, diagnostics, regenerative medicine, and contract research services. It is part of the Reliance Group, India's largest private sector company with \$67 billion in annual revenues.

- ♦ Led and executed RLS development & regulatory strategy for pharmaceutical and biologics products for regulated markets, including the U.S. and the EMA. Leading pivotal programs for biosimilars.
- ♦ Led U.S. business development for RLS products and services.
- ♦ Supported the development of esoteric diagnostic tests and services, including commercialization of CLIA certified tests and test development and validation for biotech clients.
- ♦ Supported internal programs and development strategy for early-stage Reliance technologies and molecules.

#### **2001 - 2010: Agennix Inc., Houston**

President and Chief Operating Officer: 2002-2010

Executive Vice President: 2001-2002

Agennix was a Houston-based biopharmaceutical company developing an immunotherapy licensed from the Baylor College of Medicine. One of only four novel

therapeutics whose development was advanced locally into FDA-approved pivotal global Phase 3 trials. Sold to a German biotech company in 2010.

- ◆ Led the Agennix scientific discovery and development program. Oversaw the preclinical pharmacology and toxicology program for multiple molecules and indications. Led the clinical development program, including development strategy, trial design, investigator relationships and clinical operations. Principal investigator or co-investigator on nine NIH grants totaling over \$8 million in funding.
- ◆ Worked closely with physicians and other medical professionals in defining drug profile and clinical programs, including compassionate use and scientific publications. Published and presented extensively in both the scientific and the general media – author on over a hundred presentations and publications.
- ◆ Led the regulatory strategy and served as the primary point of contact with the Food and Drug Administration (FDA), the European Medicines Agency (EMA) and other regulatory agencies. Led our lead molecule, talactoferrin alfa, from preclinical studies, through successful Phase I and Phase II studies into pivotal, global Phase III studies.
- ◆ Directed Agennix operations. Directed successful characterization and cGMP expansion of recombinant protein manufacture to commercial quality and scale. Directed patent strategy and prosecution; inventor on over 50 issued and pending patents.
- ◆ Helped lead Agennix strategy, business development and external relations, including partnering discussions, analyst meetings, investor presentations, and media outreach. Left Agennix following a successful sale to GPC Biotech.

**1994 - 2001: McKinsey & Company, Houston.**

Senior Engagement Manager: 2000-2001

Engagement Manager: 1997-2000

Associate: 1994-1997

Supported senior executives and management teams in strategic planning & execution, operations, and governance in a broad range of industries and functional areas in North America, Europe and Asia. Worked closely with both line and functional leadership and executives. Contributed to firm thought leadership through technical bulletins and publications. Selected life sciences engagements included:

- ◆ Supported a major European pharmaceutical with R&D portfolio optimization and development of processes to prioritize and manage research programs.
- ◆ Supported a major integrated healthcare system with its ambulatory clinic strategy and operations, including redefining relationship between primary/specialty care clinics and acute care facilities and operational improvement in its ambulatory network.
- ◆ Supported a mid-sized hospital system in Asia with operational improvement, including reduction in wait times (reduced ER wait times by 68%), improved throughput, and improved asset utilization.

- ◆ Supported a major U.S. academic medical center with re-defining its goals and mission, the relationship between the medical school and affiliated hospitals, its governance model, and its payor strategy.
- ◆ Supported a mid-sized biotechnology company with portfolio prioritization, product development and business development strategy

**1992 - 1994: Johns Hopkins School of Medicine, Baltimore.**

Postdoctoral Fellow in Biochemistry.

Investigated the glycosyl phosphatidyl inositol pathway for possible points of therapeutic intervention using the *Trypanosoma brucei* VSG model. Used a broad variety of molecular biological, biochemical and biophysical tools and techniques.

Founding President of the Johns Hopkins Postdoctoral Association, the first such organization in the U.S. and the model for additional organizations across the U.S.

**OTHER ACTIVITIES AND APPOINTMENTS****Center for Public Policy Priorities (CPPP), TX**

Since 2013, Member, Board of Directors

CPPP is a non-partisan research, analysis and advocacy organization focused on evaluating public policy affecting economic and social opportunity for all Texans.

**Harris Health System, TX**

2009 - 2012: Member, HCHD Board of Managers.

Chair, Joint Conference Committee

Chair, Strategic Planning Committee

The Harris Health System (Harris County Hospital District) is a fully integrated healthcare system that cares for all residents of Harris County, Texas. The system includes 16 community health centers, seven school-based clinics, a dental center and dialysis center, mobile health units, a rehabilitation and specialty hospital and two full-service hospitals. It has over 35,000 hospital admissions and over 1.5 million ambulatory visits each year.

- ◆ Active participant in system oversight and governance as a member of the Board of Managers.
- ◆ As Chair of the Strategic Planning Committee, helped frame the Harris Health System agenda and strategic plan in response to ongoing changes in the healthcare environment, including the Affordable Care Act and the 1115 Waiver. Also contributed to operationalization and implementation of the strategic plan, including participation in Operational Planning meetings.
- ◆ Participated in outreach activities with national and state legislators and policy makers in Washington, DC, in Austin, and locally.
- ◆ Contributed actively to key programs and initiatives within Harris Health by working with the executive team and through key Board committees, including the

Performance Improvement & Patient Safety Committee, the Budget & Finance Committee, the IT Committee, and the 1115 Waiver Committee.

### **Pratham and Niramaya Health Foundation**

1998 - 1999: Founder, Pratham Health, Mumbai (renamed Niramaya Health Foundation)  
Since 2000: Founding Director, Pratham USA and/or Pratham Education Foundation  
2009-2014: President, Pratham USA

Took a year's leave of absence from McKinsey & Co. to work with Pratham, a non-profit educational organization in India ([www.pratham.org](http://www.pratham.org)). Leveraged Pratham's existing infrastructure and resources to create a health program reaching 65,000 preschool children in less than six months. The program and the health organization have continued to grow in reach and scope. Pratham, the parent organization, has served over 50 million children in India and has received numerous international awards and recognition. Received the "Making a Difference Award" from Children's Hope India, New York, September 2002 for my work with Pratham and Niramaya.

### **Adjunct Academic Appointments**

Since 2002: Adjunct Professor of Management, Jones Graduate School of Management, Rice University, Houston. Teach a course on "Entrepreneurship in Biotechnology".

2003-2012: Adjunct Professor, Department of Molecular and Cellular Biology, Baylor College of Medicine, Houston.

Since 2014: Adjunct Professor, University of Texas, School of Public Health.

### **EDUCATION**

**1992: Ph.D. in Physiology**, Johns Hopkins University School of Medicine, Baltimore.

**1988: Certification by the E.C.F.M.G.**  
(Educational Commission for Foreign Medical Graduates, Philadelphia).

**1987: M.B.B.S.** University of Bombay, India. (Equivalent of M.D.)

### **SELECTED PROFESSIONAL ACTIVITIES AND APPOINTMENTS**

- ◆ Member, Health Care Advisory Committee, Greater Houston Partnership (current)
- ◆ President, TiE Houston (current)
- ◆ Member, Jones Health Care Advisory Board, Rice University (current)
- ◆ President, Indo-American Chamber of Commerce of Greater Houston (2007-09)
- ◆ Member, Life Sciences Advisory Committee, Houston Technology Center (2005-2018)
- ◆ Member, Biotechnology Industrial Advisory Committee, Univ. of Houston (2006-08)
- ◆ Member, Medical School Council, Johns Hopkins University (1991-93)
- ◆ Member, Postdoctoral Program Committee, Johns Hopkins University (1992-94)
- ◆ Founding President, Johns Hopkins University Postdoctoral Association (1992-94)

- ◆ President of Medical School Student Body (1984-85)
- ◆ Editor, Medical School Journal (1983-84)

### COMMUNITY BOARD MEMBERSHIPS:

- ◆ BioHouston (current)
- ◆ Center for Public Policy Priorities (current)
- ◆ TiE Houston (current)
- ◆ CEOs Against Cancer (current)
- ◆ Harris County Hospital District (2009-2012)
- ◆ Niramaya Health Foundation, Mumbai, India (current)
- ◆ Pratham Education Foundation and ASER Institute (current)
- ◆ Indo-American Chamber of Commerce of Greater Houston (IACCGH; 2004-11)

### SELECTED PUBLICATIONS

Safety, tolerability, and biomarkers of the treatment of mice with aerosolized Toll-like receptor ligands. Alfaro VY, Goldblatt DL, Valverde GR, Munsell MF, Quinton LJ, Walker AK, Dantzer R, **Varadhachary A**, Scott BL, Evans SE, Tuvim MJ, Dickey BF. *Front Pharmacol*. 2014, Feb 6;5:8

Randomized, double-blind, placebo-controlled phase II study of single-agent oral talactoferrin in patients with locally advanced or metastatic non-small-cell lung cancer that progressed after chemotherapy. Parikh PM, Vaid A, Advani SH, Digumarti R, Madhavan J, Nag S, Bapna A, Sekhon JS, Patil S, Ismail PM, Wang Y, **Varadhachary A**, Zhu J, Malik R. *J Clin Oncol*. 2011 Nov 1;29(31):4129-36.

A randomized, double-blind, placebo-controlled, phase II study of oral talactoferrin in combination with carboplatin and paclitaxel in previously untreated locally advanced or metastatic non-small cell lung cancer. Digumarti R, Wang Y, Raman G, Doval DC, Advani SH, Julka PK, Parikh PM, Patil S, Nag S, Madhavan J, Bapna A, Ranade AA, **Varadhachary A**, Malik R. *J Thorac Oncol*, 2011, 6(6):1098-103.

Phase IB trial of oral talactoferrin in the treatment of patients with metastatic solid tumors. Hayes TG, Falchook GS, **Varadhachary A**. *Invest New Drugs*, 2010, 28(2): 156-162.

Phase II trial of talactoferrin in previously treated patients with metastatic renal cell carcinoma. Jonasch E, Stadler W, Bukowski R, Hayes T, **Varadhachary A**, Malik R, Figlin R, Srinivas S. *Cancer*, 2008, 113(1):72-7.

Lactoferrin acts as an alarmin to promote the recruitment and activation of antigen-presenting cells and antigen-specific immune response. Rosa G, Yang D, Tewary P, **Varadhachary A** and Oppenheim JJ. *J Immunol*. 2008, 180(10):6868-76.

Lactoferrin, a major defense protein of innate immunity, is a novel maturation factor for human dendritic cells. Spadaro M, Caorsi C, Ceruti P, **Varadhachary A**, Forni G, Pericle F, and Giovarelli M. *FASEB Journal*, 2008, 22:2747-2757.

Talactoferrin stimulates wound healing with modulation of inflammation. Engelmayer J, Blezinger P and **Varadhachary A**. *Journal of Surgical Research*, 2008, 149:278-86.

Requirement for IFN- $\gamma$ , CD8<sup>+</sup> T lymphocytes and NKT cells in Talactoferrin-induced inhibition *neu*<sup>+</sup> tumors. Spadaro M, Curcio C, **Varadhachary A**, Cavallo F, Pericle F, and Forni G. *Cancer Res* 2007, 7(13):6425-6432.

Oral lactoferrin results in T cell-dependent tumor inhibition of head and neck squamous cell carcinoma in vivo. Wolf JS, Li G, **Varadhachary A**, Petrak K, Schneyer M, Li D, Ongkasuwan J, Zhang X, Taylor RJ, Strome SE, O'Malley BW Jr. *Clin Cancer Res* 2007; Mar 1;13(5):1601-10.

Phase I trial of oral talactoferrin alfa in refractory solid tumors. Hayes TG, Falchook GF, Smith DP, Davis LD, Dhingra HM, Hayes BP, and **Varadhachary A**. *Inv. New Drugs*, 2006; 24(3):233-40.

Oral Lactoferrin Inhibits the Growth of Established Tumors and Potentiates Conventional Chemotherapy. **Varadhachary A**, Wolf JS, Petrak K, O'Malley, BW Jr., Spadaro M, Curcio C, Forni G, and Pericle F. *Int. J. Cancer*, 2004; 111(3):398-403.

Purification and identification of a fatty acyl-CoA synthetase from *Trypanosoma brucei*. Jiang D, Werbovets K, **Varadhachary A**, Cole R, Englund P. *Molec Biochem Parasitol*, 2004; 135:149-152.

Properties and Application of Recombinant Human Lactoferrin to Enhance Healing of Diabetic Wounds. Engelmayer J and **Varadhachary A**. *Wounds*, 2003; 15(9): 294-301.

A point of light in Mumbai. Banerji R, Chavan M, Vaish P and **Varadhachary A**. *McKinsey Quarterly*, 2001, No. 1:156-165.

Identification of two essential arginine residues in UhpT, the sugar phosphate antiporter of Escherichia coli. Fann M, Davies AH, **Varadhachary A**, Kuroda T, Sevier C, Tsuchiya T, Maloney PC. *J Membr Biol*. 1998, 164(2):187-195.

Reconstitution of the phosphoglycerate transport protein of *S. typhimurium*. **Varadhachary A** and Maloney, PC. *J Biol Chem*. 1991, 266(1):130-135.

A rapid method for reconstitution of bacterial membrane proteins. **Varadhachary A** and Maloney, PC. *Mol Microbiol*. 1990, 4(8):1407-1411.

Anion-exchange mechanisms in bacteria. Maloney PC, Ambudkar SV, Anatharam V, Sonna LA, **Varadhachary A**. *Microbiol Rev*. 1990, 54(1):1-17.

Book Chapter: Identification and reconstitution of anion exchange mechanisms in bacteria. Chapter in *Advances in Cell and Molecular Biology of Membranes and Organelles*, 1995.

## SELECTED PATENTS

Dev Chatterjee and Atul Varadhachary. A device for sensitive, quick and quantitative point-of-use immunoassay.

Atul Varadhachary, Karel Petrak, and Rick Barsky. Oral human lactoferrin in the treatment of malignant neoplasms and other hyperproliferative diseases.

Atul Varadhachary, Karel Petrak, Rick Barsky and Bert W. O'Malley, Jr. Intratumorally injected lactoferrin in the treatment of hyperproliferative diseases.

Jose Engelmayer and Atul Varadhachary. Lactoferrin in the treatment of wounds.

Atul Varadhachary and Federica Pericle. Lactoferrin as an adjuvant to cancer vaccines.

Atul Varadhachary and Federica Pericle. Lactoferrin as an agent in the prevention of organ transplant rejection and graft-versus-host-disease.

Karel Petrak and Atul Varadhachary. Oral Lactoferrin in the treatment of sepsis.

Atul Varadhachary, Rick Barsky and Ernest Yankee. Use of lactoferrin in prophylaxis against infection and/or inflammation in immunosuppressed subjects

Atul Varadhachary, Peter Glynn, Karel Petrak and Jose Engelmayer. Composition and uses of lactoferrin related peptides.

Atul Varadhachary and Karel Petrak. Lactoferrin as a radioprotective agent.

**RESEARCH GRANT SUPPORT**

Preclinical Development of a Novel T-ALL Therapeutic Antibody. 2019-2021. Principal Investigator. DP190025. CPRIT. \$2,912,313.

Uterine wall-membrane anchor device for fetal surgery. 2019-2021. Principal Investigator. NIH/NICHD. 2R44HD094456-02. \$998,650.

Artificial urethral sphincter for control of urinary incontinence in pediatric patients. 2019-2020. Principal Investigator. 22.1R43DK123908-01. \$224,771

Physician Office-Based Urine Analyzer to Tackle Prescription Drug Abuse. 2019-2020. Co-investigator. NIH/NIDA. 2R44DA043325. \$986,127

Innovative delivery of siRNA across the blood brain barrier. 2018-2019. Principal Investigator. NIH/NIA. 1R43AG062064-01. \$224,989.

Preclinical evaluation of a novel small molecule STAT inhibitor. 2018-2019. Co-investigator. NIH/NIAID. 2R44 AI125007-02. \$999,993

Mitochondrial targeted nano-antioxidants for Alzheimer's Disease 2018. Co-investigator. 1R41AG055254-01A1. \$224,989

Targeting Synaptotagmin-2 to prevent airway mucus obstruction. 2017. Principal Investigator. 1R41HL13605701. NIH/NHLBI. \$224,576

Targeting STAT proteins for management of atopic dermatitis. 2017. Principal Investigator. NIH/NIAID. 1R43 AI131867-01. \$243,014

Ureteral stent electromagnetic removal (USER) device for pediatric patients. 2017. Principal Investigator. NIH/NIDDK. 1R43 DK115336-01. \$224,692

STAT inhibitors for asthma therapy. 2016. Co-investigator. NIH/NIAID. 1R41 AI125007-01A1. \$227,537

Nanoparticle Prophylaxis for Protection from Chemotherapy Ototoxicity. 2016. Co-Investigator. CPRIT. RP160813. \$195,665

Reduction of nosocomial infection in preterm infants, 2008, 2009. Co-Investigator. 1R44HD057744-01A1, 4R44HD057744-02. NIH/NICHD. \$3,000,000.

Treatment of sepsis with talactoferrin, 2007, 2008 and 2009. Principal Investigator. 1R43GM076741-01, 1R44GM077816-01A2, 4R44GM077816-02, 5R44GM077816-03. NIH/NIGMS. \$3,000,000.

Treatment of sepsis with talactoferrin, 2006. Co-Investigator. 1R43GM076741-01, NIH/NIGMS. \$100,000.

Recombinant lactoferrin and necrotizing enterocolitis, 2004. Co-Investigator. 1R41HD046305-01A1. NIH/NIHCD. \$115,000.

Phase II clinical trial of lactoferrin in Asthma, 2005. Principal Investigator. 2R44AI058553-02. NIH/NIAID. \$750,000.

Lactoferrin in primate and mouse models of asthma, 2004. Principal Investigator. 1R43AI058553-01. NIH/NIAID. \$100,000.

Recombinant lactoferrin and necrotizing enterocolitis, 2004. Co-Investigator. 1R41HD046305-01A1. NIH/NIHCD. \$115,000.

Recombinant human lactoferrin to treat oral mucositis, 2004. Principal Investigator. 1R43DE015914-01. NIH/NIDCR. \$325,000.

Safety and efficacy of rh-lactoferrin in diabetic ulcers, 2003, 2004. Co-Investigator 1R44AR049961-01 4R44AR049961-02. NIH/NIAMS. \$850,000.