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Global leader and serial entrepreneur in the medical device industry with multiple successes in building companies, teams, products and revenues. Experienced at bringing new products to the world market in a high growth dynamic environment. Experienced Board member and Chairman in multiple geographies. Effective expert witness.

Accomplished Senior Executive with broad wingspan and extensive domain experience

- CEO (6 companies) and/or Chairman (4 companies) –public and private – in 4 countries
- Member of Board of Directors of 10 companies
- Domain experience in Class III implantable medical devices (cochlear implants, pacemakers & leads, ICD, neuromodulation, LVADs), imaging (ultrasound, X-ray), in vitro diagnostics, software, patient monitoring
- Designed and managed multiple international clinical trials of medical devices

Savvy financial manager

- Raised capital (public and private) >\$200M. IPO on Euronext Paris and ESM Dublin
- Built revenues from zero to \$30M annual run rate in 3 years with complex new product
- P&L responsibility from small to >\$30M annual expenditure budget
- Sold three companies, participated in sale of three others

Acknowledged leader and change agent

- Proven team leader from small start up to 160-person public company
- Turned around and revitalized struggling company (three times)
- Drove culture change from local to global; from science to market; and from development to profit

Creative Contributor with strategic view

- Inventor or co-inventor on >30 patents and applications, and built intellectual property portfolio of several companies
- Many peer reviewed scientific publications
- Conducted clinical trials and gained US (FDA) and European (CE Mark) approval of many medical devices
- Developed and implemented successful global sales and marketing strategies

Education: M Eng Science, B Engineering (University of Melbourne, AU). Graduate of AICD Company Directors course

Citizenship: USA and Australia

Professional Experience

CEO and Managing Partner - Biomedical Business Resources LLC

Jul 95 – Present

A consulting and advisory service in the medical device industry, including expert witness work.

Chief Executive Officer & Director - Mainstay Medical International PLC, Ireland

Jul 09 – October 2017

A medical device company in the field of neurostimulation therapy for chronic low back pain

Worked for sweat equity refining ideas and raising capital with a \$6M+ Series A financing in 2010. Built the company, recruited key team, designed Feasibility Clinical Study with encouraging results. Closed over-subscribed \$20M Series B financing in September 2012, and led move of Company's HQ from Minneapolis to Ireland. Led successful IPO in April 2014, with dual listing on Euronext Paris and ESM of Irish Stock Exchange. Closed €30M private placement in June 2016. Designed ReActiv8-A clinical trial which led to CE Marking approval in June 2016 and start of commercialization in 2017. Designed ReActiv8-B Clinical Trial which gained IDE approval in May 2015. Planned retirement as CEO in October 2017.

Chief Executive Officer & Director - Ventracor - Sydney Australia, USA and Europe

Jan 2005 – April 2009

An Australian Public Company developing and commercializing an implantable blood pump, the VentrAssist left ventricular assist device as therapy for patients in end stage heart failure.

COO from January 2005, CEO from July 2006. Raised ~\$50M in 2006, and ~\$28M in 2007. Built global sales and marketing organizations from scratch, and grew revenue from zero to ~\$30M annual run rate in three years. Leader of ~160 people worldwide. Repositioned company from a relative unknown to the acknowledged second player in the market. Contributed to design and management of a clinical trial which led to European CE Mark regulatory approval. Developed and completed US clinical trial and prepared for PMA submission. While finalizing a \$40M convertible debt financing in mid-2008, financial crisis triggered withdrawal of lead investors. Placed company into Voluntary Administration in March 2009 with a signed term sheet for acquisition, and left.

Chief Executive Officer & Director - Ischemia Technologies Inc. - Denver, CO **1999-2004**

A VC-backed company with an in vitro diagnostic blood test for detecting cardiac ischemia.

Drove product development, clinical trials, regulatory approval, and market launch. Built 35-member team and established a scientific advisory board. Designed and started clinical trials in 1999, obtained CE mark in 2001, Canadian approval in 2002, and FDA clearance in 2003. Expanded patent portfolio from 2 to 10, and drove revenue growth. Raised VC financing of >\$25M in four rounds between 1999 and 2003. Company sold to Inverness Medical Innovations in February 2005.

Chief Executive Officer, Board Chairman - CardioComm Solutions, Inc. - Victoria BC, Canada **1997-2006**

A public software development company with products for management of real time ECG and patient data.

Joined as member of Board of Directors (1997) then became interim President & CEO from 1998. Cut costs and turned around company, restructured management team, raised new equity financing. Brought in new CEO and management team in 1999, and remained as Chairman of the Board until June 2006.

Chief Executive Officer & Director - NeoVision Corporation - Seattle, WA **1996-1997**

A medical device company commercializing a new product with 3D ultrasound image guidance of minimally invasive breast biopsy for suspected breast cancer. Joined as a consultant early 2006, and later appointed as president and CEO. Obtained 2 term sheets for VC financing, but sold the company to US Surgical for \$42 million, yielding a >4x return to shareholders in approximately 18 months.

Vice President - Telectronics Pacing Systems – Denver, CO **1989-1995**

A \$200+ million global company in implantable cardiac pacemakers and defibrillators.

VP Business Development **1995**

Led the development of the overall business strategy; strategic alliances; diversification and consolidation opportunities; coordination with potential investors; and management of the intellectual property portfolio.

VP Research & Technology **1992-1995**

Managed applied research and technology of pacemakers and leads, including IC design, applied research, and biomaterials. Managed patent portfolio and negotiated cross licensing. Managed two major product recalls.

VP Strategic Planning **1992**

Responsibility for forward planning: product strategy, diversification opportunities, and company structure. Organized customer focus groups and Scientific Advisory Board, and developed the strategic plan.

VP International Marketing **1991-1992**

Coordinated global product marketing strategies for regions outside USA. Created sales strategies and provided sales support to sales reps and customers.

VP Tachycardia **1989-1991**

Global project management function, with responsibility for coordination of product development, clinical trial, regulatory strategy, and market launch for the emerging implantable defibrillator business. Forged relationships between the R&D group and customers in major markets. Presented to FDA PMA panel meeting.

Chief Executive Officer & Director - Ausonics Pty. Ltd. - Sydney, Australia **1986-1989**

A \$30M revenue subsidiary of a public company that developed, manufactured, and distributed ultrasound imaging equipment. US distributor of OEM-sourced X-ray mammography equipment.

Joined as Chief Executive R&D in 1986, promoted to CEO in 1987. Turned around and maintained the viability of the company during a time of cash squeeze, revitalized manufacturing and marketing, removed unprofitable products, improved sales of core products, and cleaned up balance sheet. Negotiated contracts with a Japanese supplier of equipment for U.S. distribution and negotiated to sell the U.S. mammography distribution business to a Finland based company.

R&D Executive - Cochlear Corporation - Sydney, Australia **1981-1986**

World leader in implantable hearing prostheses, dominant market share, major public company.

One of the founding team. Several positions held in product development, marketing, and manufacturing. Liaised with University of Melbourne for technology transfer. Developed speech processor and speech processor programming system for cochlear implant. Wrote patents, physician manuals, user manuals, and part of PMA regulatory submissions.

Director, Northern Region Biomedical Engineering Service RNSH Sydney Australia **1978-1981**

Established and managed a Biomedical Engineering Service at a major teaching hospital at the center of a health care region (approx. 3000 beds), with responsibility for procurement and maintenance of medical technology equipment for all departments. Designed and built custom instrumentation for numerous research projects for several specialties.

Researcher Sydney Eye Hospital, Sydney Australia **1976-1978**

Designed and built equipment for the new laboratory for the founding Professor of Ophthalmology including visual evoked potentials, electroretinography, and electrooculography. Participated in several clinics, and ran training programs for ophthalmology fellows in various topics including vitrectomy, ophthalmic electrophysiology, and intraocular lenses.

Other Positions**Executive Chairman** – Docbot Inc, Irvine, California **2018 – present**

Docbot is using deep learning artificial intelligence for image processing of colonoscopy images. Initial applications are in automated documentation, followed by real time AI assisted polyp detection with the goal of improved performance of colonoscopy. <http://www.docbot.co/>

Member of Board of Directors – Quench Medical (Minneapolis MN) **2018-present**

Early stage medical device company with a new technology for delivering chemotherapy via an inhaled route. <http://www.quenchmedical.net/>

Expert in Residence – University of California Irvine **2018 – present**

Provide guidance and advice to early stage companies in the Wayfinder Seed Program (incubator)

Chairman of the Board - First Medical - Mountain View, CA **1998-2000**

Developer of a point of care immunoassay IVD test platform for biochemical markers of cardiac function. Organized restart and refinancing of the company after original VC investors declined to continue. The Company was sold to Sigma Diagnostics in 2000, yielding approximately 4x return to second round investors in less than two years.

Member of the Board, Chairman of Audit Committee – Cardiac Science, Irvine CA **1997-2005**

A public medical device company commercializing the PowerHeart Automatic External Defibrillator (AED). Merged with Quinton Cardiology Systems in September 2005.

Chairman, Medical Devices Advisory Board MDS Capital Corp. and CMDF, Toronto, Canada **1998-1999**

Expert Witness Work **1991-Present**

Worked with many law firms as an expert witness in the general areas of medical device product liability, medical device intellectual property, and contract disputes. Work included affidavits, depositions, and court appearances. Cases include:

- A major intellectual property case in the mid-1990s involving patents regarding implantable defibrillators
- A patent dispute case in 2004 involving Ischemia Technologies where the inventor of the patent on which the company was founded filed another patent and licensed it to a competitor, for Ischemia Technologies.
- A case involving an IP dispute between Sigma and Carefusion (Plaintiff) in the District Court for the Southern District of California, Civil Action 10-CV-0442 DMS (WMC)
- A matter between Stryker Corp. and Joseph P. Errico, et al. in the Circuit Court for Kalamazoo County, Civil Division, 2011-0097-CK – primarily related to “commercially reasonable efforts,” for Stryker.
- A matter between Bausch and Lomb and Dr. Sarfarazi (New York Western District, case 6:09-cv-06041) – primarily related to “commercially reasonable efforts” for Bausch and Lomb.
- A matter between two medical device companies relating to commercially reasonable efforts to achieve milestones following an M&A transaction (American Arbitration Association)
- Multiple product liability cases (for the defendant), including expert reports, depositions, and court appearances

Issued US Patents

- 10,016,603 Systems and Methods for Restoring Muscle Function to the Lumbar Spine
- 9,999,763 Apparatus and Methods for Anchoring Electrode Leads Adjacent to Nervous Tissue
- 9,950,159 Systems and methods for restoring muscle function to the lumbar spine and kits for implanting the same
- 9,861,811 Electrical Stimulator for Treatment of Back Pain and Methods of Use
- 9,474,906 Systems and methods for restoring muscle function to the lumbar spine
- 9,248,278 Modular stimulator for treatment of back pain, implantable RF ablation system and methods of use
- 9,108,053 Apparatus and methods for rehabilitating a muscle and assessing progress of rehabilitation
- 9,079,019 Apparatus and methods for anchoring electrode leads for use with implantable neuromuscular electrical stimulator
- 9,072,897 Systems and methods for restoring muscle function to the lumbar spine
- 8,876,685 Blood pump with an ultrasound transducer
- 8,858,416 Implantable medical devices
- 7,074,194 Apparatus and method for risk stratification of patients with chest pain of suspected cardiac origin
- 7,063,782 Electrochemical detection of ischemia
- 6,770,487 Bar code readable diagnostic strip test
- 6,217,744 Devices for testing fluid
- 6,106,524 Methods and apparatus for therapeutic cauterization of predetermined volumes of biological tissue
- 6,027,457 Apparatus and method for securing tissue during ultrasound examination and biopsy
- 5,851,180 Traction-inducing compression assembly for enhanced tissue imaging
- 5,820,552 Sonography and biopsy apparatus
- 5,807,234 Myostimulator control using metabolic demand and muscle performance
- 5,720,770 Cardiac stimulation system with enhanced communication and control capability
- 5,693,000 Cardiomyoplasty simulator with feedback control
- 5,476,486 Automatic atrial pacing pulse threshold determination utilizing an external programmer and a V-sense electrode
- 5,458,623 Automatic atrial pacing threshold determination utilizing an external programmer and a surface electrogram
- 5,391,192 Automatic Ventricular pacing threshold determination utilizing an external programmer and a surface electrocardiogram
- 5,311,607 Facsimile machine for printing documents all with corresponding edges aligned but without requiring scanning
- 5,292,340 Physiologically-calibrated rate adaptive, dual chamber pacemaker
- 4,532,930 Cochlear implant system for an auditory prosthesis
- 4,522,209 Cochlear prosthesis test system