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DANY BÉRUBÉ, Ph.D.

Professional experience

August 2023 – Present **Lutronic Corporation** Milpitas, CA
Vice President of Advanced Research & Innovations
- Deliver Proof-of-Feasibility for early innovative concept.
- Provide Scientific inputs for during all product development phases.
- Responsible for all scientific aspects related to product development.
- Develop high-level strategies for product pipelines, and IP protection.

June 2021 – August 2023 **Sofwave Medical** Milpitas, CA
Vice President of Scientific Affairs & Innovations
- Identify and develop strategies/products aimed at addressing existing and new market opportunities to position the company as the market leader in the field.
- Develop and manage the patent portfolio.
- Deliver "Proof of Concepts" related to product enhancements, new technologies, and new procedures.
- Responsible to provide scientific competitive intelligence to the company in order to optimally define and position Sofwave offerings.
- Publish papers in peer-reviewed Journals.
- Present the science and key benefits of Sofwave technology to Key Opinion Leaders (KOLs) and salesforce during various meetings.

2020 – June 2021 **Self-Employed** Milpitas, CA
Consultant for Sofwave Medical and Healium Medical (Israel)
- Perform FEA analysis with Comsol to model tissue heating with an unfocused ultrasonic device for the treatment of wrinkles and skin laxity in the esthetic industry, and to model an ultrasonic catheter for the pulmonary veins isolation to treat atrial fibrillation in the electrophysiology industry.
- Extensive experience in thermal analysis, acoustic, RF, microwave, and laser modeling. Experienced using PDE and moving mesh modules with Comsol, as well as Ansys, Matlab, and Solidworks.

2008 – 2020 **Candela Medical (Primaeva Medical, Syneron Candela)** Milpitas, CA
Vice President R&D – Profound Division, and Vice President of Global Business Development and Strategy – R&D
Key Achievements
- Designed, presented, and implemented a patent portfolio strategy which led to $20M in upfront payments and 2-6% royalty streams from all RF needle-based competitive products in the US. The concept was presented to the Chairman of the Board in 2010, and the ITC lawsuit successfully completed in 2019.
- Developed new market opportunities for the treatment of cellulite and submental fat reduction. Proposed and develop new sterile single-used cartridges, which now represent about 30% of Profound recurring revenues. Led all clinical and data collection activities to obtain FDA 510k clearance for the treatment of cellulite. Trained physicians and on-staff nurses on the new clinical procedures and technology.
- Led the development of a new proprietary platform technology to compete with Cryolipolysis (CoolSculpt). Identified a missing key technological feature needed for success, and successfully

completed a proof of concept study with a major US university. Led the internal patent portfolio development to protect the concept.

- Wrote and published 5 peer-reviewed articles related to Profound technology, clinical results, and science in scientific Journals.
- Trained the direct US salesforce and international distributors on Profound technology, clinical procedures, science, as well as competitive positioning.
- Led the development of Profound (ePrime/Miratone) from inception to commercial release. Lead the R&D team in the design, V&V, 510k clearance, and commercial release of a system for the treatment of rhytids and skin laxity. Led the transfer to manufacturing from the US to Israel and China. The system is commercially available and called "Profound" (see: https://candelamedical.com/na/provider/product/profound). Manage all product and software updates since the commercial release.
- Develop and implement a strong IP portfolio related to Profound technology before the acquisition of Primaeva Medical by Syneron (now called Candela Medical).
- Filed 9 patents application in 5 months in 2009 as requested by the CEO.
- Act as a hands-on scientist and performed Finite Element Analysis (FEA) to model the radiofrequency and laser interactions with biological tissues in order to investigate and/or improve several treatment concepts.

Key Roles

- Identify and develop strategies aimed at addressing existing or new market opportunities to position the company as market leader, and create value for all stakeholders.
- Develop/maintain professional connections and alliances with major research laboratories in the industry to better address clinical needs. Act as a liaison between major research laboratories and the company.
- Develop both defensive and offensive IP strategies to optimize investment returns in key market segments occupied by the company.
- Develop a strong relationship with all Research and Clinical functions to ensure insightful inputs and strategies are generated for product and procedural development.
- Work directly with R&D to deliver "Proof of Concepts" related to product enhancements, new technologies, and new procedures.
- Work directly with Product Development, Engineering, Regulatory, and Marketing to guide product development, and optimize product launch.
- Act as a Technology Leader to guide Executive Leadership in potential asset acquisitions.
- Stay current with scientific and medical literature to ensure the latest innovations, knowledge and trends are applied in the company product and IP portfolio.
- Leading by example, create a culture where Innovation, Quality and Excellence are expected and rewarded.

2005 – 2008 **MicroCube, LLC** Fremont, CA

Program Manager

- Lead a full-fledged business project within the incubator. Responsible for all aspects of the project including clinical and market needs identification, staffing, R&D, IP, Quality, Regulatory, and Clinical. The project was to design a catheter-based procedure for the treatment of atrial fibrillation.
- Identify various market opportunities in medical fields for startup projects, and serve as a Board Director for the other active projects (3) within the incubator.
- Serve as a Quality Manager and implement a Quality System from the ground up. Lead all activities, and obtained ISO 13485 certification.

2004 - 2005 **Guidant** Santa Clara, CA

Consultant

- Along with 2 other executives from AFx, delivered $65 MM of Milestone Payments related to the acquisition of AFx by Guidant.

- Responsible to transfer AFx microwave ablation technology and "know-how" to Guidant.

1997 - 2004 **AFx inc.** Fremont, CA

Program Manager

- Lead the initial development of all the AFx surgical microwave ablation products released in the market. Three surgical devices were commercially released, and two catheter were under IDE.
- Developed products and procedures to perform first worldwide off-pump ablation of AF on beating heart, as well as first worldwide minimally invasive ablation procedure for AF.
- Brought the first worldwide minimally-invasive microwave ablation surgical product for the treatment of atrial fibrillation (FLEX 10) to a full market release.
- Developed and straightened AFx IP portfolio - named in 23 issued US patents, and 34 US pending applications.
- Lead all activities to publish technical and clinical results in Scientific Peer-Reviewed Journals.
- Provided technical support to physicians in the surgical operation room and electrophysiology laboratory.
- Worked closely with CEO and Board of Director to define acceptable terms during the acquisition of AFx by Guidant.
- Established strong relationships with key international Opinion Leaders to develop and promote AFx technology.
- Analyzed competitive technologies. Defined and lead company's response in term of technology and positioning to make sure that AFx was considered as the Leader in the field.
- Managed the Faculty of major International Conferences in Cardiac Surgery and Electrophysiology to insure optimal coverage of AFx technology.
- Maintained all responsibilities of a Program Manager position, including all R&D, Engineering, Operational, IP, Quality and Finance aspects. Reported directly to the CEO.

Areas of Expertise

R&D, Medical Device, Scientific Affairs, Patent Strategy, Company Liaison with External Research Centers, Product Development, Technology Evaluation, Product Portfolio Development, Scientific Publications, Team Management, Leadership Development, Quality System, Competitive Positioning, Electromagnetic Energy Interaction with Biological Tissues, Finite Element Analysis (FEA), Treatment of Arrhythmia, Atrial Fibrillation, Esthetic Procedures, Skin Treatment, Fat Removal Procedures, Cellulite Treatment, Faculty Management, Technical Writing, V&V, Product Commercialization, Biomedical Engineering, Microwave and RF Ablation, Regulatory Clearance.

List of Publications

Berube D (1998) - PhD Thesis - Traitement des arythmies cardiaques par ablation micro-onde. Ph.D, Ecole Polytechnique de Montreal.

Berube D, Ghannouchi FM, Savard P. A comparative study of four open-ended coaxial probe models for permittivity measurements of lossy dielectric/biological materials at microwave frequencies. IEEE Trans. Microwave Theory Tech. vol. 44, no. 10, pp. 1928-34, Oct. 1996. DOI: 10.1109/22.539951.

Williams MR, Knaut M, Bérubé D, Oz MC. Application of microwave energy in cardiac tissue ablation: from in vitro analyses to clinical use. Ann Thorac Surg. 2002 Nov;74(5):1500-5. doi: 10.1016/s0003-4975(02)03951-6. PMID: 12440599.

Keane D, Ruskin J, Norris N, Chapelon PA, Bérubé D. In vitro and in vivo evaluation of the thermal patterns and lesions of catheter ablation with a microwave monopole antenna. J Interv Card Electrophysiol. 2004 Apr;10(2):111-9. doi: 10.1023/B:JICE.0000019264.14661.8e. PMID: 15014211.

Gaynor SL, Byrd GD, Diodato MD, Ishii Y, Lee AM, Prasad SM, Gopal J, Berube D, Schuessler RB, Damiano RJ Jr. Dose response curves for microwave ablation in the cardioplegia-arrested porcine heart. Heart Surg Forum. 2005;8(5):E331-6. doi: 10.1532/HSF98.20051011. PMID: 16099735.

Alexiades-Armenakas M, Newman J, Willey A, Kilmer S, Goldberg D, Garden J, Berman D, Stridde B, Renton B, Berube D, Hantash BM. Prospective multicenter clinical trial of a minimally invasive temperature-controlled bipolar fractional radiofrequency system for rhytid and laxity treatment. Dermatol Surg. 2013 Feb;39(2):263-73. doi: 10.1111/dsu.12065. Epub 2012 Dec 28. PMID: 23278964.

Alexiades M, Munavalli G, Goldberg D, Berube D. Prospective Multicenter Clinical Trial of a Temperature-Controlled Subcutaneous Microneedle Fractional Bipolar Radiofrequency System for the Treatment of Cellulite. Dermatol Surg. 2018 Oct;44(10):1262-1271. doi: 10.1097/DSS.0000000000001593. PMID: 30222637.

Berube D, Renton B, Hantash BM. A predictive model of minimally invasive bipolar fractional radiofrequency skin treatment. Lasers Surg Med. 2009 Sep;41(7):473-8. doi: 10.1002/lsm.20794. PMID: 19708063.

Alexiades M, Berube D. Randomized, blinded, 3-arm clinical trial assessing optimal temperature and duration for treatment with minimally invasive fractional radiofrequency. Dermatol Surg. 2015 May;41(5):623-32. doi: 10.1097/DSS.0000000000000347. PMID: 25915628.

Willey A, Kilmer S, Newman J, Renton B, Hantash BM, Krishna S, McGill S, Bérubé D. Elastometry and clinical results after bipolar radiofrequency treatment of skin. Dermatol Surg. 2010 Jun;36(6):877-84. doi: 10.1111/j.1524-4725.2010.01563.x. Erratum in: Dermatol Surg. 2011 Dec;37(12):1821. Hantash, Basil [corrected to Hantash, Basil M]. PMID: 20618372.

Berube D, Amir R. Energy deposition and thermal profile of a novel non-invasive synchronous ultrasound parallel beam technology for skin treatment. ASLMS, Orlando, FL, Apr. 21-25 2021.

List of Patents and Patent Applications

EP 1 240 876 A1	Directional ablation catheter with myopotential sensing electrodes
EP 1 608 279 B1	A tissue ablation system with a sliding ablating device
EP 2 309940 A4	A positionable medical system for positioning medical components on or within a body
US 6,325,796B1	Microwave ablation instrument with insertion probe
US 6,471,696 B1	Microwave ablation instrument with a directional radiation pattern
US 6,527,768B2	End-firing microwave ablation instrument with horn reflection device
US 6,817,999 B2	Flexible device for ablation of biological tissue
US 6,893,436 B2	Ablation instrument having a flexible distal portion
US 7,099,717B2	Catheter having improved steering
US 7,156,841 B2	Electrode arrangement for use in a medical instrument
US 7,301,131 B2	Microwave ablation instrument with flexible antenna assembly and method
US 7,303,560 B2	Method of positioning a medical instrument
US 7,346,399 B2	Monopole tip for ablation catheter
US 7,387,627B2	Vacuum-assisted securing apparatus for a microwave ablation instrument
US 7,393,352B2	Electrode arrangement for use in a medical instrument
US 7,497.858 B2	Apparatus and method for assessing transmurality of a tissue ablation

US 7,736,360B2	Devices and methods for creating continuous lesions
US 8,657,815B2	Delivery system for delivering a medical device to a location within a patient's body
US 10,932,848 B2	Delivery system for delivering a medical device to a location within a patient's body
US 11,065,055 B2	Devices and methods for creating continuous lesions
US 2003/0083654A1	Tissue ablation system with a sliding ablating device and method
US 2004/0106937A1	Clamp accessory and method for an ablation instrument
US 2006/0116672A1	Microwave ablation instrument with insertion probe
US 2007/0203480 A1	Surgical microwave ablation assembly
US 2010/0262135 A1	Controlled delivery of therapeutic energy to tissue
AU2003209157A8	Ablation instrument having a flexible distal portion
AU2020245366A1	Device and method for treating tissue
AU2021211369A1	Skin tightening system
WO 2004073535A2	Apparatus and method for assessing tissue ablation transmurality
WO 2020171995A1	Monopolar RF subcutaneous fat treatment systems and methods
WO2021222372A1	Treatment apparatus
WO 2023089625A1	Vector tightening