



The Challenges of Medical Device Startups: Lessons Learned Along the Way

December 13, 2006

The Emerging Enterprise Center at Foley Hoag LLP

■ Program Description

Relatively few medical device company start-ups succeed. Why? Many factors contribute: Leadership and investors may lack sufficient experience. The organization and internal infrastructure may not be developed in time. The market changes or turns out not to be as expected. Longer than anticipated product development or FDA approval, or an inability to obtain suitable reimbursement levels, can drain cash and put a financial strain on a fledgling organization. Voices of experience will describe the initiative or venture they started or were part of; help us understand major obstacles that they had to deal with; tell us what they did to overcome those obstacles; provide thoughts on why their responses worked or didn't work; outline circumstances that worked in their favor; and delineate what they would do differently if they could roll back time.

■ Moderator

David Barash, M.D., President, Concord Healthcare Strategies, LLC

■ Panelists

Jeffrey Arnold, CEO Coach, Serial Entrepreneur

Laurence Roth, Vice President Business Development and Operations, Percardia, Inc.

John Geisel, Partner, Growth Strategy Partners

■ Agenda

- 6:00 - 6:30
Networking and light dinner
- 6:30 - 6:35
MDG announcements
- 6:35 - 6:45
David Barash Introduction of topic and panelists
- 6:45 - 7:00
John Geisel presentation
- 7:00 - 7:15
Laurence Roth presentation
- 7:15 - 7:30
Jeffrey Arnold presentation
- 7:30 - 8:15
Moderated panel discussion

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■ Biographies



David Barash

David M. Barash, M.D., has been providing expert strategic and operational advisory support to healthcare investors and development stage healthcare companies for nearly 10 years. Before founding Concord Healthcare Strategies, Dr. Barash was involved in direct healthcare management for over 15 years, and has been practicing medicine since 1984. Dr. Barash served as executive vice president and medical director for Access CardioSystems, a medical device company in Concord, Mass. Currently, Dr. Barash is the managing director for Adoneh, LLC, a medical technology partnership that is developing innovative technology for critical care and resuscitation medicine. He is also the chief executive officer of Esotech Innovations, a start-up company creating a platform technology for esophageal-based critical care monitoring and therapy. He is the senior medical director of Medical Capital Advisors, an investment banking firm in Boston, and an advisory consultant to Aethlon Capital, a private equity investment group based in Minneapolis. Dr. Barash received a bachelor of arts and a medical degree with honors from Cornell University.



John Geisel

John Geisel is an experienced senior medical industry executive who has enjoyed success in large part due to his ability to understand the needs of the medical customer. He has experience with external defibrillators, MRI technology for diagnosing heart disease, anesthesia monitors, and critical care monitoring systems. He has also worked with software-based systems for arrhythmia monitoring, anesthesia information management and physician billing. Mr. Geisel's career highlights include starting the U.S. subsidiary of Datex-Engstrom, a Finnish manufacturer of medical monitoring systems, and growing revenues from zero to \$48 million. He also led start-up sales across the eastern half of the U.S. for Nellcor as it introduced pulse oximetry to the anesthesia market. More recently he was president of Access CardioSystems where he helped the company create a new presence and completed a corporate restructuring. Mr. Geisel has a bachelor's degree from the University of Pennsylvania and an MBA from Wharton. He served in the U.S. Marine Corps as a bombardier/navigator and attained the rank of captain.



Larry Roth

Laurence Roth has over 25 years of experience in the development of medical devices for both large corporations and venture-backed start-ups. At Percardia, Mr. Roth provided technical leadership while managing the development of a novel myocardial stent and associated surgical and percutaneous delivery systems. Previously at Focal Inc., he managed product and business development activities for the company's proprietary polymer technology in cardiovascular local drug delivery applications. His experience also includes 13 years of product development at the USCI Division of C. R. Bard, Inc. and 10 issued patents. He earned both bachelor of science and master of engineering degrees in biomedical engineering from Rensselaer Polytechnic Institute and has a master of business administration from Babson College.



Jeff Arnold

Jeffrey Arnold is a serial CEO of life sciences companies who advises medical device entrepreneurs on strategy and is active in company formation, financing and strategic partnerships. He was previously CEO of CardioFocus where he developed a unique catheter for treating atrial fibrillation--now in human trials. Prior to that he was founder and CEO of Cambridge Heart, a supplier of cardiology diagnostic equipment. Prior to that he was CEO of Molecular Simulations, now called Accelrys. Mr. Arnold also held senior R&D and marketing positions for Becton Dickinson and ran the medical instrumentation group for Datascope Corp. Mr. Arnold is a guest lecturer at the MIT Sloan School, a mentor at the MIT Venture Mentoring Society and is on the grant review board at the MIT Deshpande Center. He was formerly Chairman of the Board of the Greater Boston Chapter of the American Heart Association. Mr. Arnold received a bachelor's degree in electrical engineering from MIT in 1972.

■ **MDG Mission**

MDG's Mission is to contribute to the continuing development of medical devices and other medical technologies by enhancing the professional development of its members, fostering and supporting entrepreneurial thinking, serving as a forum for exploration of new business opportunities, and promoting best practices in enterprise management.

■ **MDG Officers, 2006-2007**

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■ **December Forum Co-Champions:**

John A. Merhige, Director of Business Development, Pluomed, Inc.

Howard Perlstein, Principal, HOW Management

We are always looking for volunteers to help make our forums and networking successful. Please email the chairperson if you would like to get involved with MDG.

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Medical Development Group

2006/2007 Program Calendar

- **Forum Meetings** (Silicon Valley Bank, 1 Newton Executive Park, 2221 Washington St., Newton)
 - 2006** Sept. 6 Strategic Partnerships and Alliances: Assessing, Developing and Managing Relationships
 - Oct. 4 Anticipating and Responding to Changing Market Conditions Successfully
 - Nov. 1 Seeing the Light—New Advances in Diagnostic Imaging Using Optics and Light
 - Dec. 13 The Challenges of Medical Device Startups: Lessons Learned Along the Way
 - 2007** Jan. 10 Beyond FDA—Considerations in Clinical Trial Design & Conduct (*Note: 2nd Wednesday*)
 - Feb. 7 Distribution Options for Medical Device Companies
 - March 7 Integrative Medicine: Thinking Outside the Box
 - April 11 Medical Device Project Management: Challenges & Strategies for Development
 - May 2 Medical Device Software: Assessing Safety and Efficacy
 - June 6 Physician/Clinician Relationships: Making Them Work for You
- **Networking Meetings** (Pizzeria Uno, Newton Corner, and other locations)
 - 2006** July 19 Medical Technologies: State of the Industry
 - Aug. 16 Leadership & Team Building: Developing Intrapreneurial Skills
 - Sept. 20 Delivering Care Outside the Hospital as Boomers Turn 60
 - Oct. 18 Market Research: Improving Your Product and Market Decisions
 - Nov. 15 Medicare: The Changing Rules of Reimbursement (*Location: Silicon Valley Bank*)
 - Dec. 20 Does Size Really Matter: Small vs. Larger Companies
 - 2007** Jan. 17 Medical Device Outsourcing (*Location: Silicon Valley Bank*)
 - Feb. 21 Garnering and Managing Media Attention
 - March 21 Your Intellectual Property: How Much is it Worth?
 - April 18 Risk Management (ISO 14971): A Review
 - May 16 Strategies for Pre-Clinical Development
 - June 20 Post Market Surveillance: What to Expect
 - July 18 Working with Academia
 - Aug. 15 Finding a Position in the Medical Device Industry

**If you are interested in sponsorship opportunities,
please contact Mel Prenovitz at mel@melpren.com or at 617-738-6599.**

■ Upcoming Events

December 20 Networking Meeting: *Does Size Really Matter? Small vs. Larger Companies*

Elaine Crowley, Principal, The Crowley Group, a coaching and consulting firm, will discuss the differences you can expect to find at a start-up. Working in a large company, we can easily take many things for granted, such as our roles and responsibilities, resources available to do the job, physical plant and environment, compensation, work/life balance. What kinds of people make this transition successfully?

January 10 Forum: *Beyond FDA—Considerations in Clinical Trial Design & Conduct*

An expert panel will address reimbursement requirements and human subject protections—from a cross-national perspective, comparing U.S. opportunities and requirements to those of Great Britain and the European Union.

Please pre-register for MDG events
For more information, visit www.MedDevGroup.org.