Boston MedTech Advisors (BMTA) addresses a wide range of interdisciplinary activities, helping its client companies to identify optimal strategies leading to successful product introductions, accelerated adoption of their technologies and creation of greater shareholder value, as illustrated in a number of recent examples:

- A company developing minimally invasive ablation therapy approached BMTA to assist in identifying the initial clinical indication to be pursued. The recommended strategy led to the development of a system used in office-based settings for the treatment of benign tumors. BMTA has further assisted the company in formulating its regulatory strategy, which has led to the successful submissions and market clearances for two 510(k) applications. Following successful financing, the company is starting to market its products in the U.S., launching them first in areas identified by BMTA as more supportive by third-party payers.
- BMTA assessed a number of reimbursement strategies for a new technology utilizing external electrical fields to treat brain and other solid tumors. The ambulatory treatment, which is applied continuously at the patient's home, requires frequent replacement of electrodes and other support functions. BMTA has researched reimbursement and coverage policies for other cancer treatments and for other device-based ambulatory treatments, and formulated a reimbursement strategy that addresses payer's guidelines while considering key operational, marketing, customer support and financial objectives. The company expects to start commercial activities in the coming months.
- Addressing spine problems continues to be one of the more attractive opportunities for developers of medical technologies. BMTA has been involved during recent years in a number of activities in this exciting space, assisting companies ranging from start-ups to major technology players to address diverse business issues, including evaluation of the economic value of new technologies, review of reimbursement trends and coverage policies, development of regulatory strategies, identification of post-launch barriers, development of value proposition and positioning of new products, and more. Products addressed by BMTA include visualization technologies, injectable compounds, surgical tools and implantable devices. Deploying an interdisciplinary team with direct spine-related clinical, biomechanical and marketing know-how and regulatory, reimbursement and business strategists, BMTA has successfully contributed to the development and commercialization efforts of its client companies by determining the value of their respective technologies, devising proper product and market positioning, identifying competitive threats and barriers to adoption, developing

regulatory strategies, and help sourcing clinical specialists and key opinion leaders (KOLs) to serve on advisory boards.

- BMTA has worked recently with a number of companies developing innovative monitoring technologies for the acute and post-acute markets. New monitoring technologies are facing new sets of challenges and opportunities, as acuity level of admitted patients is increasing, cost pressures are mounting, especially as payers stop paying for avoidable complications, and demands for quality and transparency of hospital care are mandated by legislators, payers and accreditation agencies. Much visibility is given to incorporation of smart alarms, connectivity with health IT networks and integration with nurses' workflow. Technologies supported by BMTA include non-invasive hemoglobin monitoring, non-contact sensors tracking changes in patient status, multi-variable vital sign monitors, oxygenation and blood perfusion monitoring, and more. BMTA addressed diverse issues ranging from development of market requirements and technical specifications, planning and executing clinical studies, developing marketing positions and market penetration strategies, assessing future needs for measurements of new physiological parameters and supporting regulatory submissions. A number of products supported by BMTA are already marketed or close to market launch.
- A company developing light therapy treatments for dermatological conditions approached BMTA after failing to obtain FDA regulatory clearance for one of its products. After developing a strategy for securing clearance allowing over-the-counter sales (as the treatment is intended to be self-administered by patients), BMTA supported the execution of a clinical study intended to demonstrate the required safety and efficacy of the device. BMTA activities included major revisions to the clinical protocol, identifying FDA-acceptable analysis modes, providing the clinical monitoring, and supporting the development of the final report, including the important statistical analysis. 510(k) premarket notification was prepared and filed with the FDA by BMTA. FDA issued a 'not substantially equivalent' determination, leading to a BMTA appeal that included a presentation to the senior staff of FDA's Office of Device Evaluation. In a rare decision, the FDA accepted the merit of the appeal and granted the OTC-designated regulatory clearance.
- We conducted an assessment of the market opportunity for a new biological product, designated by regulatory agencies as an orphan product, intended to treat certain bone defects. The objective of this project was to support a business decision as to the potential return of investment following the development and commercialization of the product. Our effort entailed extensive review of clinical literature, evaluation of the efficacy and current utilization of alternative treatments and products, and primary research to identify acceptance drivers, barriers and pricing sensitivity in all major markets, including the U.S., Germany, France and the UK. The effort was culminated with the development of a detailed analysis

assessing prevalence and actual level of interventions, anticipated penetration rates for the new treatment, pricing and revenue projections.

- Following the licensing of an imaging technology developed by NASA, we successfully developed the regulatory strategy and managed the corresponding filing leading to the first FDA clearance for the imaging technology, developed originally by NASA for remote sensing, and subsequently adapted for medical applications. The technology utilizes parallel computing to process in minutes information that otherwise may require hours, or even a few days to process, thus, enabling practical clinical use in addition to supporting complex research. The recent FDA clearance enables the company to expand its marketing efforts from research markets and start selling its products and services to hospitals and imaging centers.

- A BMTA team worked for over a year with a medical research group in a large academic medical center to advance technological breakthrough from the conceptual phase to a structured development effort. The new technology utilizes sophisticated analysis to create an objective biophysical representation of a patient's brain function by merging EEG and ERP data, in order to better quantify and monitor CNS functions. The development effort will eventually lead to the commercialization of a system intended to improve efficacy and efficiency of CNS function monitoring and diagnostics supporting a number of anesthesia and neurological care applications. BMTA efforts included analysis of competitive technologies, identifying market needs for the new technology, and planning initial proof-of-concept clinical studies.