Pulse of the industry

Medical technology report 2010

Ernst & Young

Quality In Everything We Do

To our clients and friends,

Medtech innovation has often been driven by iterative changes to existing technologies. As a result, the industry's business model has traditionally relied on venture financing, predictable regulatory and reimbursement pathways, regular physician interaction and a symbiotic M&A environment between emerging and established companies. Today, the convergence of several trends and sweeping reforms is placing tremendous strain on medtech's long-standing business model and will ultimately force the industry to innovate the way it conducts business.

Ernst & Young's third annual *Pulse of the industry* report focuses on these challenges. In two roundtables — one on innovation and the other on financing and M&As — as well as a series of guest articles, industry veterans discuss the most important issues facing the industry. Our introductory article provides a detailed overview of the key trends and implications, as well as some guiding principles for companies in dealing with these challenges. As always, our report contains extensive data on the financial, financing and transaction activity of the US and European industry, but this year the scope has been broadened to include insights on several key Asia-Pacific markets through an overview article and a roundtable on China.

Many of the seemingly disparate trends now looming before the medtech industry — from comparative effectiveness research to the consolidation of hospital purchasing decisions and changes on the regulatory and reimbursement fronts — are in fact symptomatic of a more fundamental shift: the emergence of a "health outcomes ecosystem." This is a world in which firms will no longer be rewarded based on how many units of a product they sell, but rather on their ability to deliver health outcomes — i.e., improve patient health and access — while decreasing cost to the system.

While this will undoubtedly bring challenges, the health outcomes ecosystem — which is being enabled by the intersection of health care and information technology — is, intuitively, in medtech's sweet spot. Companies in several existing medtech segments could see tremendous growth opportunities because of their ability to improve health outcomes — from enabling personalized medicine to making drug delivery more targeted and effective. Even more exciting, we are likely to see entirely new product and service offerings emerge that use medical technology in creative ways to empower patients and address the needs of payors and providers. But to unleash this potential, companies will need to innovate the process of innovation — experimenting with pilot programs and partnering with non-traditional players. Ernst & Young's worldwide organization stands ready to help you as you navigate your way forward.

— **Ernst & Young**, *Global Life Sciences Center*

Contents

Global perspectives

Industry performance

Asia-Pacific

Global perspectives

Introduction

The value of innovation

The medical technology industry faces an unprecedented confluence of challenges that promise to test many basic elements of the industry's long-standing business model: funding sources, innovation mechanisms, deal structures, regulatory regimes and payor expectations. The implications for the industry will be significant. In the years ahead, firms will need to revisit key elements of their business models — from how they raise capital to how they innovate and even to the basic question of what they sell.

In this article, we discuss these issues by grouping them into three basic challenges:

1. Sustaining innovation

2. Delivering value and outcomes

3. Fueling growth

It should be noted at the outset that this is, almost inescapably, a discussion of *average* trends and challenges. Even though we frequently refer to it in the singular — as the medtech *industry* — medtech is of course an extraordinarily diverse set of technologies and products, ranging from contact lenses to implantable devices and CAT scan machines. Individual medtech segments have different capital requirements. Their products represent different levels of complexity and patient risk, with different innovation cycles and different customers. The trends we discuss here — like sweeping changes in any industry — will inevitably produce winners and losers. They will create new risks but also new opportunities. The challenge for medtech companies in different segments will be to position themselves to seize these emerging opportunities, even as they seek to navigate the new challenges and risks. The paths taken will need to be as creative and variable as the industry itself.

> "In the years ahead, firms will need to revisit key elements of their business models — from how they raise capital to how they innovate and even to the basic question of what they sell."

Sustaining innovation

While medtech is typically classified as part of the life sciences industry, it is in many ways quite different from other life sciences segments, such as pharmaceuticals and biotechnology. The manner in which medtech firms innovate new products, for instance, often has more in common with innovation in information technology (IT) than in drug development. That distinction is particularly relevant today, as the sector's innovation model comes under unprecedented strain from trends in the capital markets, in the deal space and on the regulatory front. To appreciate the potential impact of these trends, it is important to view them in the context of the unique innovation model that has long existed in this sector.

Some characteristics of this innovation model include:

- **Short development cycles based on engineering.** The development of many medtech products primarily involves addressing mechanical and electrical engineering challenges. This is quite different from drug development, which requires understanding — and successfully intervening in — human biology. As a result, medtech development is often seen as less risky and less complex than drug development. This, in turn, means that product development cycles for many medtech products are closer to the 18-month cycles seen in the world of IT than the decade-or-longer drug-development time horizons common in biotech and pharma. The ability to bring innovations to market in a short time frame has also historically been supported by a short and predictable regulatory process.
- **Collaborative and iterative innovation.** Unlike innovation in pharma and biotech, medtech innovation has typically been conducted in collaboration with customers. The physicians who use medtech products are a valuable source of feedback on product effectiveness and design. It is quite common for a medtech sales rep or product manager to be present in an operating theater to educate physicians on optimal use while also gathering real-time user data to inform the design of future-generation products. While most innovation in drug development occurs only prior to marketing approval, medtech innovation is typically iterative and continues well after marketing approval has been secured for the first generation of a product — mirroring the innovative processes commonly seen in IT, where companies typically bring out new generations of slightly improved products every 18–24 months.

Indeed — as shown in the accompanying chart — while biopharmaceutical innovation is typically represented in a *linear* "funnel chart," medtech innovation is better illustrated as a *cyclical* and iterative process. The ideas for most new innovations come from physicians. In some cases, the idea forms the basis for a new iteration of an existing product at a large medtech company. In other cases, the innovator may seek to commercialize the idea through a new venture-backed start-up.

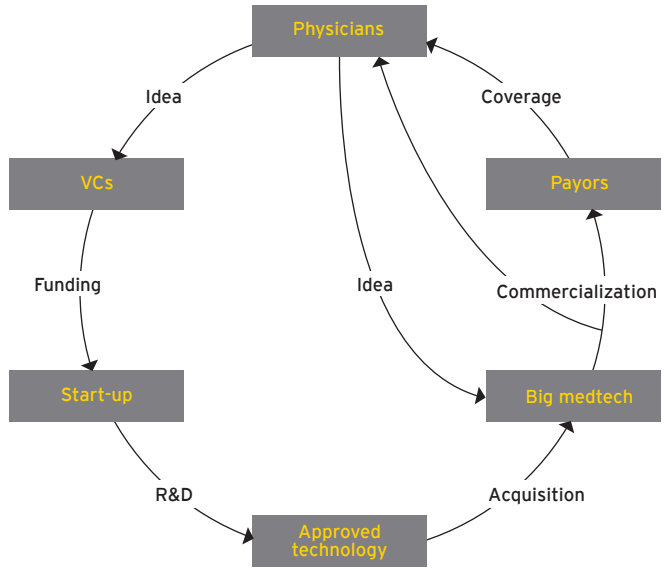
While venture funding in medtech shares some features with the funding of biotech start-ups, the VC model is in many ways closer to the model for funding IT companies. For one, the typical investment is much smaller (reflecting the shorter product development cycle) and somewhat less risky than a comparable investment in biotech. The preferred exit has been to sell the company to a large medtech buyer once the technology has received marketing approval (in biotech, by contrast, exits often occur once a product has demonstrated proof-of-concept in clinical trials).

Commercializing products has typically been the domain of large medtech companies, which have the requisite infrastructure, scale and resources. And, as already mentioned, the process of innovation continues through feedback from physicians that leads to new generations of products. In the span of more than two decades, for instance, medtech innovations to treat coronary artery disease have progressed from balloon angioplasty to stents to drug-eluting stents and, most recently, to bio-absorbable stents.

The medtech industry's innovation model is now under unprecedented strain, as it faces new challenges at almost every step of the innovation cycle:

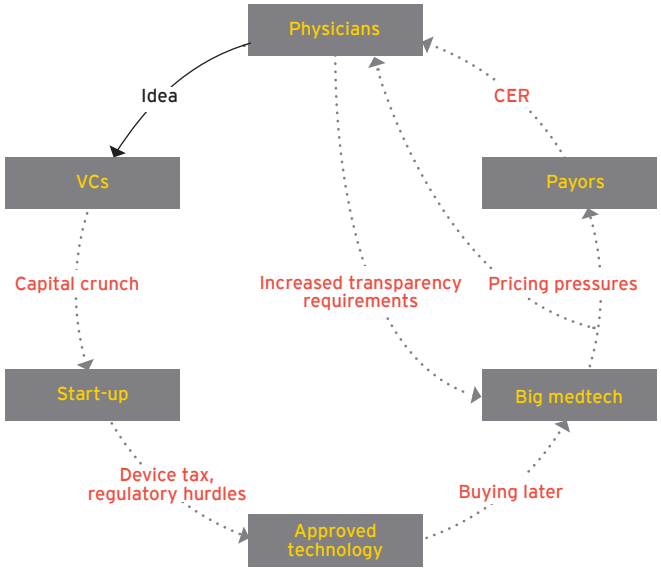
- **Venture funding.** The global financial crisis has taken a toll on the funding environment for medtech companies. While the overall funding numbers have held up reasonably well in the face of the crisis, the distribution of venture capital has become more skewed than at any time in the last decade. As the availability of capital has tightened across capital markets, there has been a corresponding decline in venture capitalists'

Medtech's long-standing "cycle of innovation"...

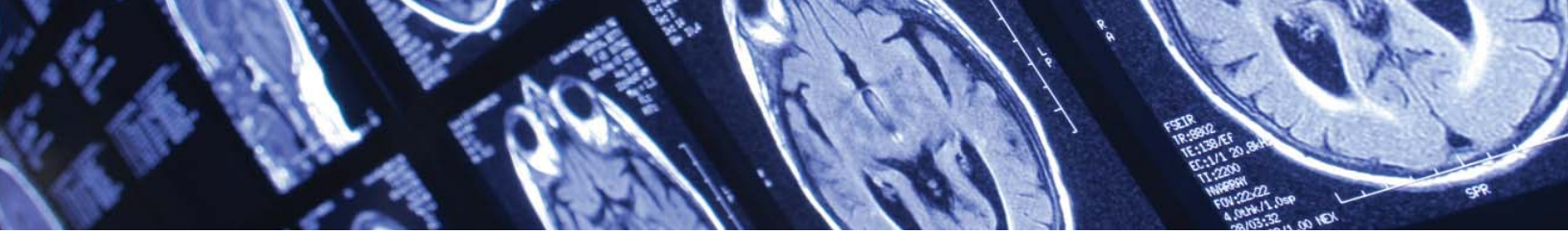


Source: Ernst & Young

... now faces new challenges at every stage



Source: Ernst & Young



ability to raise funds from limited partners. With exits relatively scarce and considerably more challenging, VCs are having to carry their portfolio companies further, which means they have proportionally less money available for new investments.

- **Research and development.** With many emerging medtech companies having less access to capital, they are having to do more with these diminished means. Firms are having to deploy capital more efficiently and are seeking operating efficiencies through measures such as restructuring and outsourcing. Beyond the immediate impact of capital constraints, the process of obtaining marketing approval for products is itself becoming more challenging, with the looming prospect of restrictions on the long-standing 510(k) process for clearing products in the US (discussed in greater detail on pages 6 and 7). The industry is also concerned about the newly imposed "device tax" under the US health care reform legislation, which is anticipated to have a disproportionate impact on smaller, pre-profitable companies.
- **Exits through acquisition.** As discussed earlier, acquisitions have traditionally provided the vast majority of exits for investors in emerging medtech firms. In the past, the buyout of a small company usually occurred once it had received marketing clearance — a logical transition point since it is more efficient for large firms, with their resources and economies of scale, to commercialize newly approved products. In the current environment, however, strategic buyers have become much more risk averse and are increasingly interested in buying assets that have already gained market acceptance and demonstrated growth potential. In the US, the "sweet spot" for attracting buyers now appears to be US$40 million–US$100 million in sales and a clear path to profitability.

  This may make perfect sense from the perspective of a large buyer — and represent a reasonable response to an increasingly uncertain reimbursement environment — but its implications for innovation in the current climate are worrisome. Small companies, already squeezed by capital constraints and girding for the prospect of a device tax and higher regulatory hurdles, are now also being forced to deploy precious capital to commercialize products before they can attract a buyer. This not only puts these firms under increased financial strain, but also is a sub-optimal use of resources. It is not ideal for most small companies with no prior product-commercialization experience to develop sales and marketing infrastructure that will ultimately be regarded as redundant by a buyer anyway. And the timing could not be worse. Requiring small firms to build commercial infrastructure is an inefficient use of capital at precisely the moment when the industry needs greater capital efficiency.
- **Iterative innovation with physicians.** Many in the industry are also worried about new strains on the connection between physicians and medtech firms — a vital link in the iterative cycle of innovation. The US Sunshine Act, in particular, will place greater scrutiny on payments to physicians. But this is not by far the only example. The trend toward increased transparency in interactions with physicians is visible in many key markets. The US law, it should be noted, does nothing to ban payments — it merely requires companies to monitor and report them — but the threshold for physician payments is very low, and as David Hochman points out in the *Roundtable on innovation* article, there are fears that some hospitals may overreact by placing new restrictions on contacts between doctors and medtech firms.

"… while biopharmaceutical innovation is typically represented in a *linear* "funnel chart," medtech innovation is better illustrated as a *cyclical* and iterative process."

> "Requiring small firms to build commercial infrastructure is an inefficient use of capital at precisely the moment when the industry needs greater capital efficiency. "

Delivering value and outcomes

Even as medtech companies grapple with the challenge of sustaining and funding innovation, they face a future in which the fruits of that innovation will be under more scrutiny than ever before. This challenge is being driven by three trends:

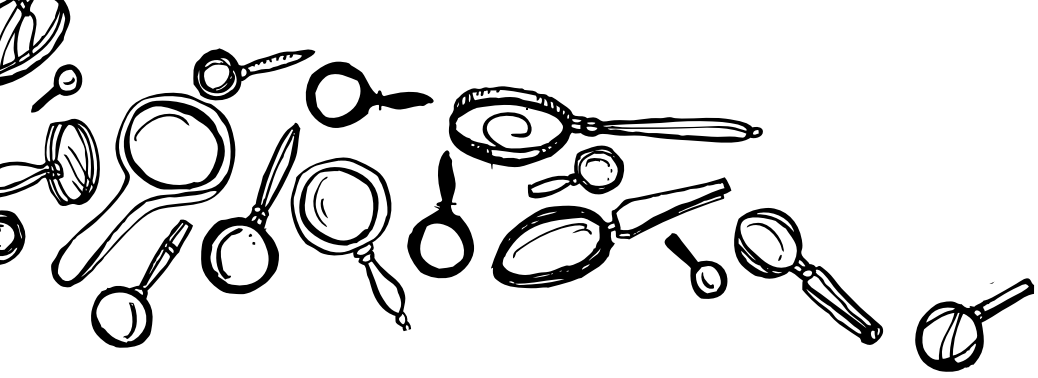
1. Comparative effectiveness research
Comparative effectiveness is not a new concept in the life sciences. From health technology assessments to the "fourth hurdle," the principle of comparing medical interventions to determine how relatively effective they are has been around in various forms. These ideas have been gathering steam in recent years, as governments and payors try to rein in escalating health care costs. In the UK, for instance, the National Institute for Clinical and Health Excellence (NICE) has been conducting cost-utility analysis for about a decade to inform coverage decisions by the country's National Health Service.

So far, medtech has been largely exempt from this trend. While many medtech companies are used to conducting clinical trials for regulatory submissions and to help set pricing, comparative effectiveness research (CER) conducted by third parties to determine whether a product should be given coverage is not widespread. To some extent, this is because drugs have simply been more amenable to CER approaches. Drugs account for a larger share of health care spending than devices and diagnostics, and blockbuster drugs and high-priced cancer biologics have been tempting targets for payors. Since medtech markets are often smaller and more fragmented, applying CER techniques to devices and diagnostics has been a less attractive proposition. Measurement is another issue — unlike drugs, which are simple to administer, the efficacy of devices depends at least in part on the skill of the user, which can generate noise in outcomes data. In addition, the short product-innovation cycles in medtech have made CER considerably more challenging — by the time a comparative effectiveness study focusing on a particular product is completed, it could easily be dated by the arrival of the next-generation product.

But change is coming. The Obama Administration's stimulus-spending package, passed in February 2009, allocated US$1.1 billion for CER. And it is clear that much of that budget will be applied to medtech products. Indeed, when the Institute of Medicine (IOM) released its list of 100 initial priority topics for CER in June, the list included a number of medtech-specific items, from imaging technologies to stenting to robotic-assistance surgery. Given the challenges in conducting CER at the individual-product level in an industry with such short innovation cycles, it is not surprising that the IOM list focuses instead on comparing entire medtech regimens to alternative medical interventions. (For more on the impact of CER on the medtech industry, refer to "Preparing for comparative effectiveness research," by Wendy Everett.)

2. Hospital consolidation
While CER on medtech products may largely be conducted on entire classes of products, companies will also be subject to cross-product scrutiny because of another trend: the consolidation of purchasing decisions at hospitals. Historically, doctors at most hospitals in the US have had relative freedom to use the products they most preferred. In recent years, however, many hospitals have started reducing the number of options in any product class and requiring physicians to choose from a smaller menu of options.

Hospitals are focusing like never before on developing robust procurement functions, which are charged with squeezing costs out of the system. These procurement offices are much more inclined to look at medtech suppliers holistically — wanting, in other words, to manage the relationship with an entire enterprise as opposed to different product groups or member companies.



A closer look

Reduced margins and increased creativity: health care reform's impact on US hospitals

Venson Wallin
Ernst & Young, LLP

The recently passed US health care reform legislation has ambitious and laudable goals: improving quality, lowering costs and increasing access. However, the law will squeeze hospitals' margins, which will in turn increase the pressure on their medtech suppliers. To stay competitive, medtech firms will need creative pricing and partnering approaches.

The new law mandates reductions in Medicare and Medicaid reimbursement, and many believe that commercial insurers will likely follow suit. Hospital margins — already a razor-thin 2% to 3% — will be squeezed even further by increased costs from new quality and compliance requirements and higher patient volumes.

As hospitals try to protect their margins, medtech firms can expect challenging negotiations over proposed price increases, for example to pass on the medical device tax contained in reform law. Hospitals will also look to limit the variety of medtech products they carry. Whereas they previously often stocked several similar products to suit individual doctors' preferences, this has been changing in recent years, and the shift will likely gain increased momentum with mounting margin pressures. And, as many doctors become hospital employees in the years ahead, more of them will be affected by this trend.

These financial trends may also limit hospitals' ability to access debt markets — traditionally an important source of funding for large equipment purchases. Capital markets require that borrowers have stable operations and can project a strong margin. Since the details of health care reform implementation will depend on rules to be issued over the next few years, this could create uncertainty in lenders' minds about the stability of the health care industry. Meanwhile, the tightening of hospitals' margins discussed above will further constrain hospitals' ability to raise capital for large purchases — forcing many to make do with existing equipment.

As a result, we could see increased sharing of equipment such as CAT scans across hospitals. Some providers have already formed joint ventures to share technology within a region, and such arrangements will become increasingly common. Critically, this is also an opportunity for medtech firms to develop creative partnerships with providers to facilitate the use of their technology. For example, a health system may work with a medtech firm in developing a new device through research and testing, and the subsequent marketing of the device may be shared by the health system and the medtech firm. Medtech firms selling big-ticket equipment will also need to identify potential financing alternatives for buyers.

The legislation also mandates many quality and compliance measures that will have to be reported. Hospitals will have financial incentives to comply, and the federal government will also utilize the data to post comparative measures on web sites for consumers. This is a significant opportunity for medtech firms to develop innovative means of monitoring a patient's episode of care and providing the hospital with the measurement and documentation methodology for complying with the regulations. ▶

These trends are likely to accelerate because of the financial crisis, which has increased the pressure on hospitals' operating margins. In addition, the reform of health care is expected to add to the pressure on margins in many markets as reimbursement levels are lowered and costs raised due to new quality and compliance requirements. (For more on this trend, refer to "A closer look," by Venson Wallin, on the previous page.)

These trends could also increase the visibility of third parties that can help providers manage such challenges. Access MediQuip, for instance, offers a device management platform that promises to procure implantable devices and assume the financial responsibility and risk of obtaining reimbursement while allowing hospitals to offer their doctors flexibility in choosing from a broad range of implantable devices.

As hospitals look to carry a smaller number of products in each class, it will become critical for companies to focus on the value proposition of their product offerings compared to those of their competitors. Meanwhile, succeeding with procurement offices that are interested in dealing with suppliers holistically will require companies to align processes, incentives and performance measures to prevent turf battles.

3. Marketing approval

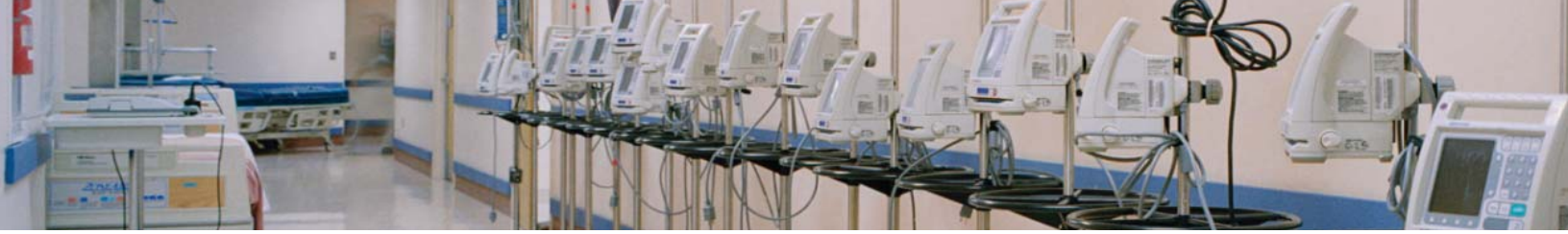
The process by which medtech products are given marketing approval or clearance is substantively different from the way in which drugs are approved. This is, in large part, a reflection of the unique nature of medtech innovation that was discussed above. Specifically, the fact that much of medtech innovation consists of iterative improvements to existing products has meant that regulators have developed distinct mechanisms for granting marketing clearance for such products. And the tremendous diversity of medtech products and technologies has resulted in a system where different mechanisms are used to regulate products carrying different levels of patient risk.

In the US, for instance, where the approval of medtech products has only been regulated by the FDA since 1976 (as compared to the approval of drugs, which the agency has regulated since the 1930s), medtech products are grouped into three classes according to the extent of oversight needed to ensure product safety and efficacy:

- Class I — products that have a low risk of injury or illness and do not support or sustain human life (e.g., elastic bandages, examination gloves and bedpans)
- Class II — products that carry a higher risk than Class I products and are usually non-invasive (e.g., X-ray machines, infusion pumps and dialysis catheters)
- Class III — products that are life-supporting, life-sustaining or carry a high risk of illness or injury (e.g., implantable pacemakers and heart valves).

Class I and Class II products go through a relatively short clearance process — premarket notification, more commonly known as 510(k). This subjects manufacturers to *general controls* (e.g., manufacturer registration with the FDA, compliance with good manufacturing practice standards, proper branding and labeling) and, in the case of Class II devices, *special controls* (e.g., labeling requirements, mandatory performance standards and post-marketing surveillance).

On the other hand, Class III products — for which there is insufficient information to assure safety and efficacy using only general and special controls — require a premarket approval (PMA), a more extensive process that includes clinical trials.



This system has come under increasing fire in the last couple of years as a growing chorus of voices has argued that the 510(k) system needs to be reformed. Critics have cited anecdotes of a product that was marketed without being either approved or cleared by the FDA and another for which the FDA allowed the company to determine whether a 510(k) filing was necessary. In October 2008, several scientists from the Center for Devices and Radiological Health (CDRH, the branch of the FDA that regulates medical devices) wrote a letter to Congress calling for legislation to "modernize" the 510(k) process and alleging that senior management at the FDA was improperly interfering in the approval or clearance of products. In January 2009, a study by the US Government Accountability Office (GAO) found that a number of Class III devices were being cleared using the 510(k) process instead of the required PMA process. In September 2009, the FDA responded to these concerns by asking the IOM to conduct a review of the 510(k) process. Meanwhile, the FDA has been proceeding with its own 510(k) review. Its 510(k) Working Group held a public workshop in February 2010 and released preliminary recommendations in August.

Among other things, the preliminary recommendations call for the creation of a new class of medical device – Class IIb. These devices, which may include implantable or life-sustaining/life-supporting products, would typically require clinical and manufacturing data in the 510(k) notice. They would also be subject to additional post-marketing requirements, such as "condition-of-clearance" studies. The recommendations also called for clarifying the conditions under which multiple predicates can be used in determining whether a device is substantially equivalent to an existing device, and potentially disallowing the practice of "split predicates" (when one predicate is referenced for intended use and another for technological characteristics).

The industry has expressed concerns about restricting the 510(k) process, arguing that the existing system provides regulators with flexibility and has a strong track record of ensuring patient safety without hampering innovation. The potential restrictions would add to an environment where the pace of 510(k) clearances has already slowed considerably and companies are increasingly concerned about the uncertainty and opaqueness of the process. Companies are also uneasy about the FDA's "corrective fix" pilot recall program, under which they can be required to recall older models of products after new versions have been introduced, even when there are no consumer complaints about the old versions.

Regulating medical products has always involved striking a fine balance between being too lax (failing to protect patients from unsafe products) and being too restrictive (failing to let potentially beneficial products reach patients in a timely manner). Striking that balance for medtech products is not easy, given the tremendous diversity of products and technologies and the rapid, iterative nature of innovation in this industry. The various stakeholders will continue to debate these issues in the months ahead, but it seems clear that some tightening of the clearance process is likely. In the US, the 510(k) process will still account for the majority of product approvals, but the data requirements are likely to increase, and a greater portion of devices are likely to follow the PMA route in the future.

The health outcomes ecosystem

These three trends – comparative effectiveness research, increased scrutiny and pressure from hospitals, and a higher marketing-

> "... health care is no longer just for health care companies. Non-traditional entrants – IT firms, retail giants, insurers, food companies, telecommunications providers, global conglomerates and many others – are already entering the fray, sensing new opportunities in the business of delivering health outcomes."

> "It would intuitively seem that the health outcomes ecosystem — which is being enabled, after all, by the intersection of health care and information technology — should lie in medtech's sweet spot."

approval bar from regulators — are more than a coincidence. On the contrary, they are symptomatic of a fundamental shift — the emergence of a new *health outcomes ecosystem*. We are moving toward a future in which all companies in the health care arena — not just medtech firms, but also drug companies, providers and others — will increasingly find themselves in the business of delivering health outcomes. They will, in other words, be rewarded not based on how many units of a product they sell, but rather on how effective those products are in improving the health of patients.

We are being propelled toward this future by several trends. The widespread adoption and meaningful use of electronic health records (EHRs) — being heavily encouraged in the US by incentives in the Government's economic stimulus package — will vastly increase the volume of data that can be mined to compare the efficacy of different treatments. Large systems, such as Kaiser Permanente and Intermountain Health, have already been doing this, and new entrants in the EHR business such as Google Health and Microsoft HealthVault could take "value mining" to an entirely new level.

Health care reform measures — not just in the US or Europe but also in China and other major markets — are basically about the drive to increase equitable access to quality health care while simultaneously lowering costs, which only heightens the pressure on payors and governments to do more with less. To increase efficiency across the system, payors will focus more than ever on the value products deliver relative to their cost.

Consumers will be at the center of this new ecosystem, as IT — the great leveler that has already democratized countless industries, from journalism to retail trade — empowers patients as never before. Social media networks — from PatientsLikeMe to Sermo and Medscape Physician Connect — are making data on outcomes and efficacy more transparent and freeing it from the control of medtech and health delivery companies. Mobile phones are enabling patients to monitor their own health in a myriad of new ways — using everything from apps for the latest smartphones to SMS-message platforms that can expand access for patients in rural areas and emerging markets.

And health care is no longer just for health care companies. Non-traditional entrants — IT firms, retail giants, insurers, food companies, telecommunications providers, global conglomerates and many others — are already entering the fray, sensing new opportunities in the business of delivering health outcomes.

These trends are discussed in considerable detail in the 2010 edition of Ernst & Young's annual report on the pharmaceutical industry, *Progressions*. In that report, we call the health outcomes ecosystem "Pharma 3.0," reflecting that the pharmaceutical business has already been through a couple of rounds of reinvention. The daunting challenges associated with pharma's patent cliff have, in other words, driven firms to replace Pharma 1.0 (the blockbuster model in which companies were organized for top-line growth) with Pharma 2.0 (in which companies manage for the bottom line, with specialized products and an emphasis on efficiency).

Medtech, of course, has never had the equivalent of a 2.0 business model, because it has never faced as urgent a driver for change as pharma's patent cliff. To some extent, therefore, the challenge confronting medtech companies is even greater — they must simultaneously adapt to the equivalent of both 2.0 (managing for the bottom line) and 3.0 (restructuring themselves for the health outcomes business).

There is certainly evidence that firms are moving in this direction. Even as medtech firms are looking for growth in emerging markets and greater efficiencies to protect margins (distinctly 2.0 initiatives), they are introducing new technologies that empower patients and providers with real-time data on outcomes. In just one disease category, diabetes, Lifescan (a Johnson & Johnson company) has developed an app for Apple's iPhone that allows patients to upload and store glucometer data on their phones and share them with providers. The company has also collaborated with t+ Medical, a UK-based supplier of telemedicine solutions, to develop a coordinated system that transmits data from glucometers to a central database. Patients can then receive simplified information on their mobile phones. Meanwhile, Medtronic has launched a new device, Paradigm Veo, which alerts patients when their blood glucose levels fall. Bayer Diabetes Care has launched DIDGET, a blood glucose meter for children with diabetes, that connects directly to Nintendo gaming systems.

It would intuitively seem that the health outcomes ecosystem — which is being enabled, after all, by the intersection of health care and information technology — should lie in medtech's sweet spot. That would suggest that there are opportunities for many more applications than we have seen so far — which has mostly been in the area of mobile/wireless devices. The currency of the health outcomes ecosystem is information, and harnessing the power of information — capturing, measuring, sharing and monetizing it — will require innovative new technologies.

But to capitalize on these opportunities, firms will also need new ways of doing business and executing transactions. The real opportunities may be to experiment through pilots and to partner — including with non-traditional players. This is an industry where the deal space has traditionally been dominated by M&As, but firms will have to increase the number of strategic alliances in the mix.

.

Fueling growth

While medtech has fared better than most industries in the current economic downturn, it has been far from immune to the downturn's effects. After growing at a brisk pace for several years, the revenues of the US- and Europe-based industries were essentially flat in 2010 compared to 2009. And with overall economic growth stagnating in the West — and economists debating whether we are heading for a dreaded "double-dip" recession — the industry's short-term growth prospects are uncertain.

The real challenge for medtech companies, however, will be fueling growth in the *long term*. Medtech firms — long accustomed to being treated as growth stocks — are already finding themselves trading down from the handsome multiples they commanded not too long ago. Investors, wary of higher regulatory and reimbursement hurdles, are giving firms little credit for their R&D spending, and even acquisitions are often insufficient to move the needle on a company's valuation.

So where will growth come from?

While each company will need to evaluate its own circumstances, strengths and vulnerabilities when identifying drivers of growth, we believe that much of the answer can be boiled down to one word: diversification.

Product diversification

As we stated at the outset, medtech is an extraordinarily diverse industry. So it is somewhat paradoxical that, despite the

"Medtech firms — long accustomed to being treated as growth stocks — are already finding themselves trading down from the handsome multiples they commanded not too long ago."

> "... as the industry faces tremendous new risks in the future, it may make sense for companies to look at diversification not just as a way of tapping synergies and lowering costs, but also as a means of diversifying risk and expanding into different revenue streams."

tremendous breadth of activities across the industry, individual medtech companies have often been fairly narrow in their focus. Even some of the largest firms in the sector derive the vast majority of their revenues from one therapeutic focus, such as cardiovascular devices in the case of Boston Scientific or orthopedic devices for Stryker.

Ironically, this lack of diversity at the company level is at least partly driven by the tremendous diversity at the industry level. The wide variance in medtech's product types and areas of therapeutic focus means that there is often little overlap between different segments. Consequently, two medtech segments may have little in common in terms of R&D capabilities, sales and marketing approaches or regulatory requirements, such that the potential synergies to be gained from combining them — the textbook justification for mergers — are weak at best.

But as the industry faces tremendous new risks in the future, it may make sense for companies to look at diversification not just as a way of tapping synergies and lowering costs, but also as a means of diversifying risk and expanding into different revenue streams.

One approach would be to diversify into the areas within medtech that are best positioned to benefit in the new ecosystem. If every risk or challenge also contains the seeds of opportunity, then part of the answer may be in segments that could really make a difference in delivering health outcomes — in other words, segments that can have the biggest impact on boosting effectiveness or lowering costs. For instance, as drugs are increasingly pitted against each other by comparative effectiveness, innovative drug delivery technologies could help tip the balance in favor of a therapy by helping it to target more specifically, thereby increasing its efficacy and reducing side effects. Wireless and remote patient monitoring technologies could similarly see strong growth because of aging populations and the uptick in chronic diseases.

As pricing pressures from payors ramp up, companies may also want to consider segments that could be relatively immune to these trends. For instance, the focus on outcomes will increase the impetus for personalized-medicine approaches, and many research-tools companies — particularly those building the sequencers and other specialized equipment used in identifying biomarkers — will likely see strong demand for their products. The attractiveness of this segment is further enhanced by the fact that these products are typically sold to other companies or to academic institutions for research purposes, which means they are often not subject to reimbursement and, therefore, unlikely to face pricing pressures from payors.

Offer diversification

Beyond diversifying into other products, companies could also consider diversifying beyond products altogether, by expanding into services and solutions. Once again, this mirrors moves seen in the world of IT, where computer manufacturers responded to commoditization and shrinking margins by getting into the higher-margin business of affiliated services. Examples include Dell Computer, which acquired Perot Systems in 2009 to expand into IT services, and IBM, which sold its PC division to Lenovo and reinvented itself as a services company.

The DePuy Healthcare Solutions Group offers a suite of consulting services to help hospitals improve the performance of their orthopedic services. The services focus on reducing length of stay, increasing capacity and improving staff and patient satisfaction, while reducing the overall cost of the episode of care.

In January 2010, Stryker completed its acquisition of Ascent Healthcare Solutions, a leading provider of medical device reprocessing and remanufacturing services. Through the acquisition, Stryker expands into a service — helping hospitals recycle medical products such as blood pressure cuffs that would otherwise be thrown away — which should be in demand in the increasingly cost-conscious, efficiency-driven health outcomes ecosystem.

Geographic diversification

If one answer to the challenge of sustaining growth is to consider diversifying into other technologies or services, another answer may be to diversify geographically. This is an approach that many firms have been gravitating toward by increasing their focus on emerging markets. As growth in mature markets slows, and as their products face intense pricing pressure and increased scrutiny in these locations, the rapid advancement of emerging markets is looking increasingly attractive. Health care reform in China and growing middle classes with increased access to medical care across several emerging markets promise to create rapidly expanding pools of new customers for medtech firms. As discussed in the Asia-Pacific section, the medtech industries in most of these economies continued to grow briskly last year. It is hardly surprising that an emerging-market strategy has effectively become a must-have component of any mature medtech company's planning.

But to unlock the potential that is latent in these geographies, medtech firms will need to approach innovation in emerging markets very differently. With lower income levels and a shortage of health insurance, many patients in these locations will be unable to afford Western companies' products for the foreseeable future. If the majority of patients in emerging markets cannot afford Western products at Western prices, companies will need instead to offer locally targeted products at locally relevant prices. Indeed, many firms are already pursuing this approach, as highlighted by several panelists in our "Roundtable on innovation" article. Medtech companies are developing stripped-down versions of their products for emerging markets that do not have all the features of their latest-generation offerings but still provide effective results at a lower price point.

This sort of thinking — applying medtech's creativity and innovative strengths not just to developing new products but, indeed, to the innovation process itself — will be needed in spades in the years ahead. As medtech's innovation model comes under unprecedented strain, and as companies are called upon to do more with less while defending the value of their products, we are likely to see creative new approaches to innovation. The next section describes some of what we might see, and identifies principles that firms should keep in mind as they navigate the challenges ahead.

Outlook: the value of innovation

In last year's *Pulse of the industry*, our introductory article was titled "The certainty of innovation." As companies faced an environment of endemic uncertainty, we argued that the one thing they could be certain about was that truly innovative products would always be needed and the market would find ways to pay for them.

A year later, some of that uncertainty is being removed and the picture is becoming clearer. Health care reform has become the law of the land in the US. China is implementing reforms, and similar reform measures are under way in many other markets. The US market has also seen passage of the device tax and the release of preliminary recommendations on 510(k) reform. The specter of comparative effectiveness remains real, and the IOM's release of a list of top 100 priorities has helped identify the technologies most likely to be targeted. But the relative reduction of uncertainty is

> "Of particular concern, though, is the outlook for innovation. The innovation model has now developed a chasm between what buyers and regulators require and what investors and emerging companies can provide."

> "Today, the danger is that we may be moving to a system that will not adequately value each incremental innovation — and in the process, we may deny patients the tremendous potential benefit from the sum of those iterations."

not necessarily bringing good news — the picture that is emerging, unfortunately, is one where medtech companies will face greater scrutiny and significant new challenges.

The road ahead

It is clear that the pressures identified above will only increase with time. Health care reform measures are poised to increase coverage, inevitably raising the pressure on costs. As CER is conducted, most industry insiders expect that it will be used in some way to make determinations about coverage — regardless of what legislative prohibitions may say today. Weak growth in the US economy — the prediction of most economists — will bring no quick relief for medtech companies.

We expect the number of companies to shrink. Venture capitalists will probably fund fewer new firms in the foreseeable future. The constraints in global capital markets are unlikely to be eased and revert to pre-recession levels anytime soon. As they face longer paths to exits, VCs will need more funding per portfolio company, while firms looking for venture capital will continue to face a higher bar.

Meanwhile, financial pressures will drive consolidation. The higher cost of development (particularly for companies that find they now need to conduct clinical trials) will require scale economies and lead some firms to consolidate.

Of particular concern, though, is the outlook for innovation. The innovation model described in this article has now developed a chasm between what buyers and regulators require and what investors and emerging companies can provide. The regulatory changes discussed above will inevitably increase the time to approval and cost of development of many products. Partly as a response to these trends, strategic buyers are requiring companies to commercialize their products before considering a takeout. The obvious implication for start-ups and their investors is that it will take more time and money to reach an exit.

In theory, this would not be an issue if VCs simply started investing larger amounts for longer periods of time — something they already do when they invest in biotech companies. The problem, however, is that this would create a fundamental mismatch between the risk and reward of medtech investments. Investors take bigger risks in biotech because of the larger potential rewards — a successful drug can command a relatively high price tag and enjoy many years of patent protection. But in medtech, the potential payoffs are smaller, because competitors can often engineer around IP, and a product's life may be measured in months rather than years. Meanwhile, other trends, such as the downward pressure on prices and margins, are expected to further lower potential payoffs and exacerbate the growing mismatch between risk and reward. Investors are familiar with "high-risk/high-reward" and "low-risk/low-reward." But they may rightfully balk at being squeezed into a *high-risk/low-reward* model.

Beyond the strains on the funding of innovation lies a more fundamental issue: whether these trends could disrupt the iterative cycle of medtech innovation, and what we stand to lose if that happens. The fact is that while many medtech innovations are relatively small, their cumulative impact over time can be enormous. Consider pacemakers, which have been around for well over half a century. The earliest pacemakers were powered by alternating current and had to be plugged in to electrical outlets — with obvious implications for patient mobility and for morbidity in the event of a power failure. Implantable pacemakers were invented in the late

1950s, and over time, the devices have become progressively smaller, less invasive, longer lasting and more powerful. Whereas implanting a pacemaker once required opening the patient's chest, they can now be attached to the chambers of the heart through a vein — sometimes even as an outpatient procedure under local anesthesia. Unlike the inflexible devices of years past that paced the heart at one fixed rhythm regardless of the patient's needs, today's pacemakers can sense intrinsic heart rhythms and pace the heart only when needed (to encourage heart activity and better quality of health). They offer a large number of parameters that can be programmed via telemetry to suit a patient's needs. All of this has brought tremendous benefits to patients. But none of it happened overnight. It took countless iterations by numerous competitors over several decades to develop today's minimally invasive, maximally flexible devices. Yet any single iteration along the way may have provided only a small incremental benefit. Today, the danger is that we may be moving to a system that will not adequately value each incremental innovation — and in the process, we may deny patients the tremendous potential benefit from the sum of those iterations.

Rules of the road

How will companies need to proceed? Again, each firm's answer will need to be based on individual facts and circumstances, but we offer some guiding principles below.

1. **Demonstrate value proactively.** The changes described above will bring an unprecedented level of scrutiny to medtech products and prices. To thrive in this environment, companies will need to be proactive and proceed on several fronts.

   It is likely that much of the CER conducted with respect to medtech products will target *entire product classes.* As such, companies will need to identify the products most at risk (e.g., those on the IOM list or items with relatively high price tags). In these categories, firms should consider conducting their own CER (it may even make sense to collaborate with competitors to defray high costs, since the CER is targeting their products too). Demonstrating value will also require companies to define the appropriate value measures (possibly in collaboration with payors) and then build the processes and systems to capture the relevant data.

   Meanwhile, as hospitals look to winnow down the number of products purchased in each category, they will increasingly compare *individual products* within each class. Companies will need to be proactive in identifying the products most at risk and then exploring ways of increasing their attractiveness through, for example, new pricing models or offering different price/feature combinations.

2. **Innovate innovation.** Innovation is no longer just about conducting product R&D. It is also about bringing creative new approaches to the R&D process itself — innovating innovation. Some possible approaches include:

   - **"Whittle down" innovation —** As discussed earlier, many medtech firms are developing and selling "whittled down" versions of their products in emerging markets — products that offer a good deal of functionality at a more attractive price point. It may make sense for Western companies to partner with local firms, which are often able to better understand local market needs, as well as how to engineer products that best suit those requirements. Indeed, there are numerous examples from other industries of local firms developing popular products for local conditions. A few years back, India's Tata Group developed a US$2,500 car for the Indian market, and the Indian Government recently showcased a tablet device that was widely compared in the media to Apple's iPad — for the astounding price of US$35.

> "... if the industry can be certain that medtech innovation will produce value, it can no longer take for granted that that value will be recognized by buyers."

- **"Trickle up" innovation —** The experience of medtech and other industries offers another insight: whittled-down products developed for emerging markets can often gain considerable traction in mature markets as well. For instance, netbooks — the smaller, more basic versions of laptops that first exploded into the personal computer market a couple of years ago — have their genesis in the One Laptop Per Child organization's mission to develop affordable computers for children in developing countries. But computer manufacturers soon found that there was also tremendous demand in high-income countries for inexpensive computers that are "good enough" for most day-to-day needs. Such "trickle up" innovation (to borrow the term coined by *Wired* magazine) may be increasingly relevant for medtech in the years ahead as firms are subject to increasing scrutiny from payors and providers in the US and other mature markets. Companies may find that for buyers in these markets, more is not always better.
- **"Pick your size" innovation —** We are already seeing examples of "whittle down" and "trickle up" innovation in medtech. But the industry's engineering culture suggests that this could be taken even further through customer customization. Computer makers such as Dell, for instance, have built successful business models around allowing customers to configure products to their liking — giving them a large menu of possible features with different price tags. To be sure, medtech products may be challenged to offer the same degree of flexibility — particularly if each configuration would need marketing clearance from the FDA or other regulatory agencies — but it is certainly feasible that medtech firms may allow large customers to "bolt on" the features they consider most valuable.

3. **Collaborate.** While deals have always been a critical part of the medtech industry, most transactions have either been in acquisitions of smaller companies or mega-mergers among leading players. To succeed in the health outcomes ecosystem, however, companies will need to rely more heavily on strategic alliances than they have in the past. This will require them to develop specialized functional capabilities and skill sets. The challenge will be further heightened by the fact that some of these collaborations will likely be with non-traditional entrants in the ecosystem — and that partnering with dissimilar firms will involve dealing with different innovation models, corporate cultures, attitudes toward IP and levels of regulatory experience.
4. **Preserve the ecosystem.** While some industry consolidation seems inevitable — and could even be a regenerative process — medtech innovation has relied on a healthy ecosystem of companies of various sizes. With many firms facing a challenging funding environment, it is more important than ever that companies pay attention to preserving the medtech ecosystem. While emerging medtech companies have traditionally relied on venture capital, in the current environment, small companies will need to search creatively for other financing options as well. And large firms and public-sector entities could help sustain the future supply of innovative technologies — while investing in undervalued assets — through the establishment of corporate venture arms and incubators. There has certainly been evidence of such activity in this downturn — recent examples include a new European medical device incubator established by Medtronic and Sofinnova Partners and a new cardiovascular-focused incubator on the campus of the Cleveland Clinic that was launched with the help of an US$83 million grant from the state of Ohio.

Over the years, the innovative technologies and products that medtech companies have brought to market have delivered tremendous value for countless patients. There are still significant unmet medical needs to be tackled, and medtech innovation certainly has the potential to help address these needs in the years ahead. But if the industry can be certain that medtech innovation will produce value, it can no longer take for granted that that value will be recognized by buyers. The future for medtech companies is one where the value of innovation will have to be *demonstrated*. To position themselves for success, companies will need not just to address the challenges in these trends but also to seize the latent opportunities. ▶

James V. Mazzo
Advanced Medical Technology Association
Chairman
Abbott Medical Optics
Senior Vice President

Life-changing innovation

We have good reason to feel proud of the role that the medical technology industry plays in advancing patient health and improving the quality and efficiency of health care systems across the world. Every medtech company — no matter how large or small or what it produces — supports the creation of life-changing innovation. We enable better diagnoses, improved treatment options and enhanced outcomes. And through our innovations, we touch nearly every aspect of care and allow patients to become more independent, productive and fulfilled.

Over the past few decades, medical technology has had a significant impact on patient care. Thanks in large part to innovations from our industry and others in the life sciences, overall life expectancy in the US is up by more than three years, while mortality from heart attacks, strokes, breast cancer and a host of other conditions has been cut dramatically. Disability in the elderly has been reduced by one-quarter.

I am equally proud of the economic contributions our industry makes in providing high-paying, high-tech jobs even in these trying economic conditions. As Ernst & Young demonstrates in this report, the medtech industry is a vibrant and growing contributor to the US economy, generating US$197 billion in revenue and employing over a half a million workers in 2009 alone. And these are high-paying jobs: a recent Lewin Group report notes that earnings in the US medtech industry are 40% higher than the national average.

While these numbers are impressive, what is perhaps more impressive is how the industry has weathered the recent economic turmoil. Although not immune to the downturn, the industry's revenue and number of employees held steady in 2009, according to Ernst & Young.

But past performance is no guarantee of future success. Many stakeholders take for granted that medical advancements will continue indefinitely — just as we expect our computers and cell phones to always improve. But medical innovation — and the economic and patient benefits it creates — does not just *happen*. Without supportive public policies and the ability for investors and innovators to make returns commensurate with the risk they undertake, medtech innovation could well be threatened.

That caution is particularly relevant today, as our industry faces many challenges around the world. In the US, a new excise tax will be levied on the industry beginning in 2013 — and the potential burden on smaller, entrepreneurial companies is particularly disturbing. The European Commission is developing legislation that will substantially alter how medical devices are regulated in Europe. And Chinese authorities are adding additional clinical trial requirements to numerous classes of devices before they can be approved in that country.

Now more than ever, we need to preserve an environment that supports medtech innovation.

Regulatory decision-making by the US Food and Drug Administration and other global regulatory agencies must be predictable and timely and follow reasonable, risk-based standards of evidence. These agencies need to strike an appropriate balance between providing timely access to new medical advancements and ensuring patient safety. In the US, many in the industry are concerned that this balance has become increasingly skewed, with regulators growing excessively cautious because of safety concerns.

Reimbursement, whether from private insurers or government-run programs, needs to provide adequate payment for products offering clinical benefit. As major markets move toward comparative effectiveness approaches, it will be all the more important for companies to focus on demonstrating the value of their innovation and for payors to support adequate pricing for products and services that are truly innovative.

Tax policies need to encourage R&D investment and support start-ups and smaller companies, which compose the vast majority of companies in the medical technology sector.

Intellectual property, which is the lifeblood of our industry, needs strong protections. At the same time, governments should support policies that encourage free trade and not erect barriers that prevent foreign manufacturers from fairly competing with local companies.

It is our responsibility to make sure that all stakeholders understand what's at stake: without supportive public policies, it is not just innovation that suffers but also the patients who depend on our life-saving and life-enhancing advancements. ▶

Andre-Michel Ballester
Sorin Group
Chief Executive Officer

Europe industry perspective

Qualified resilience and new challenges

The global financial and economic crisis has so far had little impact on most of the European medtech industry. This statement — which could well have been paraphrased from the 2009 annual reports of a number of European medtech firms — sounds like good news. But it also contains two important qualifiers, both of which have implications for the sector's outlook in the months and years ahead.

The first qualifier is the word "most." Indeed, the majority of companies have seen little-to-no decline in their business. In Europe, a large proportion of medical devices are sold to private and public hospitals and are ultimately paid for by local social security systems, with or without a fixed reimbursement price. Acute care in particular — including segments such as major surgery or intensive care units — tends to be fairly recession-resistant and has held up well in the downturn. With the volume of hospital sales relatively unchanged and pricing that has been (somewhat surprisingly) stable, sales growth has not changed from previous years.

But not all segments have escaped unscathed. In particular, companies that manufacture devices for outpatient care (e.g., dental, ophthalmic and cosmetic surgery) have experienced mid-to-high single-digit drops in sales volume. For instance, a leading European dental company's 2009 annual report states: "Throughout the year, a large proportion of patients postponed elective procedures while others even interrupted ongoing treatment." Manufacturers of large equipment for diagnostics, imaging and hospital infrastructure have seen a slowdown in capital investment, particularly in the private sector. The number of orders has decreased for some manufacturers while the selling cycle has increased.

The second qualifier in the opening sentence is the phrase "so far." While there is good news in the fact that large-equipment manufacturers and some outpatient care companies are experiencing a slow but real recovery in the first half of 2010, challenges lie ahead. European governments are running severe budget deficits and have all already embarked on aggressive cost-cutting programs. Remarkably, medical devices have so far been largely exempt from these cuts. But generic and branded drugs have already been targeted, and medical devices can expect growing pricing pressure in late 2010 and early 2011, when new country budget targets will be introduced. Some industry leaders foresee a new market segmentation, moving from the traditional three-segment concept (high-, middle- and low-end products) to a two-segment concept: a reduced high-end, clinician-driven segment where products are clearly differentiated and innovative; and an enlarged low-end market where product differentiation will matter less and therefore price will be of paramount importance. We are already seeing such a shift in a number of European countries (e.g., Germany) where new technologies, some with limited clinical experience, are highly valued, while the prices of more commoditized products are continually eroding. However, other models may be more challenging for innovation in countries with centralized decision making (UK) or with significant regional differences (Italy).

Meeting new challenges

Innovation remains critical for success in this business. But technology and innovation alone are no longer enough. European medtech companies need to learn new skills that have traditionally been the forte of pharmaceutical firms, such as conducting health care technology assessments. They will also need to focus on making policy-makers aware of the industry's important contributions — from the European industry's hundreds of thousands of high-skill jobs and billions in R&D spending to its development of life-saving products and contribution to increased health care efficiencies.

New challenges tend to create new opportunities. For the European medtech industry, seizing the opportunity will require that it show policy-makers how its devices and technologies can save and improve patients' lives, and that it can partner with them to better control total health care costs while creating high-wage, high-skill jobs. ▶

Kazuaki Kitabatake
Terumo Americas Holdings
President and Chief Executive Officer

Asia-Pacific industry perspective

Looking to Asia-Pacific for growth

The Asia-Pacific region is a strong and growing market for medical-technology manufacturers due to its huge population and strong economies — the continent accounts for 60% of the world's population and more than 35% of global economic output, nearly as much as the US and the European Union combined. While Japan and China attract the most attention, private health care expenditures in countries such as Australia, India and Indonesia are expected to experience double-digit growth rates during the next few years — significantly higher than predicted growth in the US.

Although Japan's recent economic growth has been low compared with that of neighbors such as China and India, it is still the world's second-largest market for medical devices. The country will remain an important market for medical devices because of its wealth, its comprehensive national health insurance system, which guarantees coverage for its entire population, and its large and growing number of elderly patients. More than 22% of Japan's population was over the age of 65 in 2008 — the highest percentage in the world — and the Japanese Government projects that this number will reach nearly 40% by 2050.

China's medical device and diagnostic market is estimated to total US$8 billion and is growing 15%–20% per year. Last year, US medical technology exports to China totaled US$1.3 billion, an increase of 21% over the previous year. China's Government in 2009 launched an ambitious health care reform initiative, pledging to invest US$123 billion over 10 years to expand coverage and build and update medical facilities throughout the country, which will only increase opportunities in this sector. China's medical care is quite advanced in major cities — where private facilities would rival those in any US metropolis — but still rudimentary in rural areas, where the Government is focusing the majority of its efforts. Challenges include China's regulatory system (product registration and post-market surveillance), which contains duplicative and overly burdensome processes. Another challenge is China's reimbursement system, which is largely non-existent, with most patients paying out of pocket for major procedures. As the Government looks to develop a more comprehensive reimbursement system, it is focusing on cost containment, which some manufacturers fear could fail to account for the value of advanced technology.

India is also a market with tremendous potential for our industry. India's population has huge unmet health care needs — the country has a medical technology market about one-third the size of China's, despite having roughly the same number of people. India's population of 1.1 billion is expected to exceed China's by 2030, and its economic growth rate of more than 8% is producing a rapidly expanding middle class — from 170 million people today to more than 400 million by 2025. Our industry's challenge will be to continue to provide high-quality medical devices and diagnostics that more Indian patients can afford.

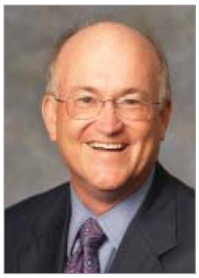
Asia-Pacific's huge population and its strong economic position on the world stage make it a medical-device market that will continue to grow in importance in the coming years. To take advantage of opportunities in this rapidly growing region, companies will need to focus on developing offerings that meet the needs of patients in these markets. ▶

Roundtable on innovation

Innovating innovation

Stephen Oesterle, MD
Medtronic, Inc.
Senior Vice President for Medicine and Technology

Rafael Torres
GE Equity
Healthcare Industry Leader



Don Jones
Qualcomm Incorporated
Vice-President Business Development, Health & Life Sciences

David Hochman
Orchestra Medical Ventures
Managing Partner

Medtech has always been an innovation-driven business. Yet the innovation model that the industry has long relied on now faces growing pressure. The venture capital that emerging companies have needed to develop breakthrough technologies has become more constrained. Exits have become more difficult, with a largely dormant IPO market and many acquirers looking for companies that have already commercialized their technologies. Potential challenges on the regulatory and reimbursement fronts – including comparative effectiveness and possible changes to the FDA's 510(k) clearance process – will likely lengthen the process of commercializing new products and technologies.

To gain a better understanding of the current and future state of medtech innovation, we caught up with four leaders who are at the forefront of medical technology creation and convergence. The panelists include **Stephen Oesterle**, who evaluates cutting-edge technologies and treatment modalities for Medtronic, and **Rafael Torres**, who leads the health care team at GE Equity and manages the US$250 million GE Healthymagination Fund. Our panel also includes **Don Jones**, who is responsible for guiding Qualcomm's expansion of wireless technologies into the consumer health, health care and medical device markets, and **David Hochman**, a managing partner at Orchestra Medical Ventures, an investor in early-stage life sciences companies.

Ernst & Young: What is the current outlook for medtech innovation? What are the biggest threats to the industry's innovation model?

Oesterle: It is the best of times in the sense that we're seeing some of the most interesting technologies imaginable. Two areas that have great opportunity include biotechnology and wireless technology. The promise of biotech's restorative, and in some cases curative, benefits are real, but most of its therapies require complicated delivery schemes. I believe medtech will increasingly fill the gap with its uncommon ability to fuse biologics and delivery devices to treat disease and improve human wellness. Meanwhile, the wireless infrastructure – broadband networks, telemetry and encryption – has finally reached a point where we can use implantable devices to accurately manage large groups of patients remotely.

Unfortunately, it's also one of the most challenging times in medtech, as investors have lost their enthusiasm for early-stage investments supporting new technologies. That's the biggest threat to innovation today – how will these emerging technologies be financed? Historically, Medtronic has often relied on the innovative technologies coming from small, emerging companies. As VC investment has become scarcer, emerging companies have been approaching us earlier than we've ever seen, looking for collaborations and/or

venture financing. Unfortunately for them, Medtronic is not a venture firm.

Hochman: Today, we are seeing greater demand for medical therapies that improve outcomes, reduce costs and speed procedures. While we're enthusiastic about the opportunities ahead for innovation to meet this demand, as Steve mentioned, the lack of venture funding — particularly early-stage funding — continues to be a problem. Adding to that, the regulatory environment in the US and Europe is becoming stricter. The result is that the time and cost involved in advancing a technology will continue to increase, and we may ultimately find ourselves facing an innovation gap. That doesn't mean the industry won't continue to come up with important innovations and breakthroughs, but it will also have to come up with more efficient ways to develop new products, or else many of the best solutions will never find their way to patients in the marketplace.

Torres: Many companies used to rely on large acquisitions as a means to innovate. However, we're complementing this with collaboration with emerging companies to drive innovation. GE recently launched its healthymagination initiative, which focuses on collaboration to develop better health solutions and increase patient access globally. Since increasing patient access is paramount to us, we've adopted a program focused on "reverse innovation," which involves developing versions of certain products by peeling away non-essential, high-cost bells and whistles. This allows developing markets to afford and have access to important technologies.

Ernst & Young: How will companies need to adapt their approach to innovation in the current business environment?

Jones: We are starting to see medtech take advantage of wireless connectivity, as some companies are now looking at how to enable quick iterations of product designs so they can deploy new features faster. Just as Apple rolls out a new iPhone every year or so, medtech companies could roll out a new version of a device every year — in effect, multiple successive submissions for new and improved models.

Torres: As I mentioned earlier, larger companies may need to rethink business models that are dependent on acquisitions for innovation and growth. Increasingly, companies are turning to collaborative ventures to accelerate innovation and pave the way into new markets. Companies are also finding that demand for the newest technology is only a piece of the puzzle. Looking ahead, we'll need to be much more objective about what truly constitutes a medical innovation — it's not just about new technology, but new technology that reduces costs, helps improve outcomes and speeds procedures.

Hochman: I agree with Rafael. Cost, efficacy and efficiency will be increasingly significant in future business model strategies. Ultimately, it is not how much money you save today on a given procedure but rather how that lower-cost procedure impacts the long-term, overall cost of health care. In the US, we've been largely cost-insensitive for a long time, but cost is now going to have to factor into how every constituent thinks about a new medical technology.

Oesterle: We'll have to figure out how to become more efficient with development so we spend more on research. This is important, since we'll likely need to shoulder more of the research and early-stage development that has normally been filled by emerging companies, which are now under a significant funding strain. We'll also work toward decentralizing our R&D efforts around the world. The bulk of our growth over the next decade is probably going to come outside the US. Therefore, it is critical that we undertake R&D in each of the

"We've been cost-insensitive for a long time, but cost is going to have to factor into how every constituent thinks about a new technology."

critical emerging markets. We need to be nearer the bedside, whether in Israel, China or the Czech Republic.

> "You cannot develop high-value, high-impact medical technologies without physician involvement. And it seems only fair that if they play a role in a product's successful development, doctors should benefit in some way."

Ernst & Young: Payors in major markets are increasingly moving toward comparative effectiveness-based approaches. What will companies need to do to succeed in this environment?

Torres: We need to come up with an integrated approach that looks at the totality of care for the individual. In this new equation, care is the objective and the driver, as well as the cost. How do decisions change when viewed as part of the bigger picture of health? Payors need to move away from a focus on à la carte health care and instead base decisions on more comprehensive health outcomes.

I'm very excited about what's going on at GE, because this integrated approach is driving innovation as well. Consider the full cost of absenteeism, which is often inadequately addressed. When a person needs six weeks to recover from open surgery, versus two weeks for minimally invasive surgery or two days for non-invasive surgery, the cost differential because of patient downtime can be significant. So it's not just about the direct cost of a procedure or technology, but rather about delivering value to the system by improving the overall cost of treatment.

Jones: Comparative effectiveness is a big deal to us, but indirectly. Together with Eric Topol, MD, Scripps Health and The Gary and Mary West Foundation, we've formed the West Wireless Health Institute, which is the world's first clinical research institute on wireless health; one of the institute's key missions is to perform comparative effectiveness research from both a clinical and a health economics perspective. A key focus for medtech companies regarding comparative effectiveness should be on the ability to provide valuable, actionable information back to the end user. The real paradigm shift for health care will be to arm the patients in a timely manner with information that they can better use to self-manage.

Oesterle: Companies will need to employ well-designed, larger-scale, randomized clinical trials that show comparative effectiveness. The challenge for small, venture-backed companies is that most do not have the time, money or clinical capability to conduct the type of large-scale clinical trials we undertake at Medtronic. We expect that the old paradigm of releasing a 510(k) product into the market and letting the market determine its application and reimbursement will no longer be valid. So we're basically approaching every new technology in our pipeline as a potential premarket-approval product — we're designing clinical trials to show that a product is safe and efficacious, but also that it's technically superior and saves the system money. We expect increasing levels of scrutiny of approved products, so it will be crucial for our success to develop a very sophisticated post-marketing surveillance network.

Ernst & Young: Despite growing acceptance, drug-device combination products still face obstacles. In the new era of delivering value to the health system, how can medtech firms encourage the adoption of such products?

Oesterle: Some of the most interesting R&D projects at Medtronic involve drug-device combinations. While these combinations have the potential to produce breakthrough products, the differences between the business models of the device and drug industries also present significant challenges. We think that the FDA will continue to approve products that combine biologics with drug delivery devices as combination products, but they won't be interchangeable. As such, Medtronic

will continue to work with the regulatory agencies to help them recognize that these combination products are new, unique devices. This will often be accomplished by undertaking clinical trials that exhibit their safety and efficacy. The continued build-out of combination product business models will be important, as I believe there are very few interesting biologics that will be applied without devices.

We need a new mindset and a willingness to work with regulators and have an open dialogue with them. Focusing on diseases with the highest burdens or greatest unmet medical needs may produce a sense of urgency and encourage willingness to test drug-device combination products and work out the obstacles. Greater harmonization of regulations globally could produce more of these open dialogues and again help improve the speed and effectiveness of care.

Hochman: The line separating drugs and devices will become increasingly blurred, as collaborations will enable important advances in the delivery of therapeutics. Medtechs and their partners will have to rationalize the regulatory and reimbursement process for combination drug-device products that can truly improve outcomes and costs. For example, if a combination product can substantially improve patient compliance, then this should translate into tangible, persuasive clinical and cost benefits for both the patient and the payor.

Jones: We need guidelines to clarify the approval process from both the pharmaceutical and device perspective, particularly when some of the information already exists for the individual product components. A similar challenge exists in my industry, as we see an increase in wireless health products where both an FCC and FDA review may be necessary, yet a collaborative approval process has not been established. However, the FCC and FDA just took their first steps toward defining a mutually agreeable process in a meeting that drew more than 500 participants to Washington, D.C., this past July. At Qualcomm, we also have an effort under way to develop what I call end-to-end communication architecture – processors and radio topologies that potentially the FDA could look at and fast-track review. These standards would also clearly define the roles of the FCC and FDA to avoid both overlap and gaps in the approval process.

Ernst & Young: Medtech innovation has often benefited from collaboration and feedback from physicians who use medtech products. How big a threat does the Physician Payment Sunshine Act pose to medtech innovation?

Hochman: You cannot develop high-value, high-impact medical technologies without physician involvement. And it seems only fair that if they play a role in a product's successful development, doctors should benefit in some way. Should these transactions be transparent and fully disclosed? Absolutely. But the Sunshine Act also increases the risk that hospitals and institutions will overreact and create their own internal policies that add layers of red tape and other barriers to physician involvement in technology development. If that's the case, physicians may be dissuaded from or grow disinterested in developing medical technologies, which will hurt new product development. I think we're already starting to see some of these trends emerge.

Oesterle: I couldn't agree with David more. I would wager that 95 out of 100 medtech products are conceptualized by physicians at the bedside; unfortunately, many reputable institutions – whether hospitals or universities – don't fully understand theimportance of the medtech company-doctor innovation paradigm. Yes,

"... developing countries may actually out-accelerate the developed countries in adopting medtech innovation. Virtual primary care, in particular, is one area where emerging markets are going to drive the development of connected devices."

these collaborations often involve the transfer of money for a physician's ideas and/or intellectual property – but it doesn't mean the relationship itself is tainted. The industry needs to figure out a way to work more seamlessly with the physicians who are the source of much of the innovation in medtech.

Ernst & Young: What role will emerging markets play in medtech innovation? Will the ways in which companies innovate for patients in these markets need to differ from approaches used in North America or Europe?

Torres: There is a tremendous opportunity in emerging markets that should not be underestimated. With the latest wave of health care innovations and technologies, there is the ability to propel emerging market populations into the world of 21st-century medicine. Areas that have not had adequate diagnostic equipment or resources in place will begin to see tremendous point-of-care innovations that will enable new ways to access health care. And access itself will be less and less constrained by physical location as new tools create the means for virtual access. Another potential development is the broadening of definitions around trained medical staff – and developing technology for professionals who can help close some of the access gaps, especially in rural areas.

Jones: I think Rafael hit the nail on the head, and I'll take it one step further. It's a relatively easy bet that developing countries may actually out-accelerate the developed countries in adopting medtech innovation. Virtual primary care, in particular, is one area where emerging markets are going to drive the development of connected devices. In a developed country, patients can see a doctor for diagnostics, monitoring or treatment. But in a developing country, there may not be enough doctors for all patients to see, so they're willing to take on the risk, and opportunity, of having a device to actually manage care.

Oesterle: We need to develop products customized for specific emerging markets. But some of these technologies can also be applied in developed-country markets. For example, Rafael's company (GE) created a handheld echocardiogram machine for India but then quickly recognized that the product also had a market within US hospitals. In that vein, we're working on a leadless pacemaker for emerging markets. While this product is being developed in response to the lack of trained electrophysiologists, if we can get the technology right, I may one day want to have one implanted.

Hochman: Emerging markets may also provide a faster track to regulatory approval and commercialization. If a company can create momentum in markets such as Eastern Europe, China, India or South America, it can use this initial experience in commercialization and proof of concept to help gain financing or form partnerships for advancing its products in developed countries. However, gaining a good foothold in those countries will require a strong understanding of patient and physician preferences and other key business factors, and these will likely differ in important ways from the requirements in the US.

Ernst & Young: Wireless or "connected" devices have tremendous potential for improving patient outcomes and delivering value to the health care system. What must manufacturers do to demonstrate the clinical and economic benefits of e-health devices and justify appropriate levels of reimbursement?

Jones: Wireless health is about taking advantage of the world's most pervasive utility, a cellular signal. Companies are developing a variety of business models – clinical, therapeutic, therapeutic management, interventional, monitoring and so on – where connectivity changes what has historically been done within health care. Most medtech companies have traditionally focused on improving the clinical value of devices. But with the clinical process taking so long, firms are increasingly focusing on providing other benefits by adding connectivity to their products even while they are gathering clinical evidence.

Torres: We were talking earlier about how companies need to show population-wide benefits to justify higher reimbursements. But to do this, they will often need to measure costs and benefits holistically –

across the system. For example, placing a new mobile-technology-enabled device in the home of a diabetic patient may save the system money in the long term because of better monitoring. But the burden of proof is currently on medtech companies – they need to come up with both the solutions and the financial justification for the solutions. The good news is that with connected products, you can analyze usage patterns and collect far more data so that you're ultimately better armed for reimbursement discussions.

Hochman: An interesting element of the potential impact of wireless technology on health care is the role of the consumer and consumer spending in creating new business models to support and enable medical innovations. In some ways, this space will attract investment because the business model may not depend entirely on traditional reimbursement. For example, we are beginning to see new wireless-enabled health care services that connect consumers directly to their physicians or physicians' offices, creating more efficient interactions for patients and doctors alike. In many cases, the success of these services will be based on consumer out-of-pocket spending rather than traditional payor reimbursement. In an environment where reimbursement requirements are getting more and more stringent, wireless health care technology may offer investors new, differentiated opportunities. These will, of course, come with new, unfamiliar challenges as well.

> "Fifteen years from now, Medtronic will look surprisingly like a services company – using broadband networks and data communication to remotely manage patients' health and their devices."

Oesterle: I agree with the prior comments – there is no doubt that wireless technology will be a key driver of medtech's success. One example where we see wireless technologies and devices playing a role right now is in congestive heart failure. Currently, US$35 billion a year is spent in the United States alone on hospitalized patients with congestive heart failure. However, since congestive heart failure takes a long time to develop, if a provider could remotely monitor pulmonary pressures of patients before they develop the condition, it could keep 30%–40% of these people out of the hospital. That is millions of patients, and billions of dollars worth of savings, to the health care system.

Wireless devices are going to reduce clinic visits and reduce the service burden of following up on patients while saving the system money. Between cutting-edge implantable technologies, smart phones, data encryption, broadband networks and supercomputers that can manage vast amounts of data storage and analytics, the infrastructure for wireless medicine is already in place. Fifteen years from now, Medtronic will look surprisingly like a services company – using broadband networks and data communication to remotely manage patients' health and their devices. ▶

Wendy Everett, ScD
New England Healthcare Institute
President

Preparing for comparative effectiveness research

Most Americans first became aware of comparative effectiveness research (CER) when the infamous "death panel" debate broke out in early 2009, soon after Congress had allocated US$1.1 billion in economic stimulus funding to begin a major expansion of federally supported CER. Critics contended at the time that CER findings would lead to government-led health care rationing.

Representatives of the US medical device industry and other health care industries had already been engaged in serious discussions with Congress over CER for many months. These were some of the major concerns of the medical device industry:

- The industry believed strongly that federally supported CER should focus on the clinical effectiveness of products and not on cost-effectiveness.
- The industry was concerned that CER studies would focus disproportionately on comparisons of discrete technologies (drug vs. drug or device vs. device) and overlook evidence that the effectiveness of competing drugs or devices might be tied to distinct patient subgroups.
- The industry argued that CER studies should not be linked directly to, or become the sole grounds for, health care coverage and reimbursement decisions.
- The industry sought high standards of transparency in the commissioning, design, execution and dissemination of CER studies.
- The industry sought a role for all major stakeholder groups — including patients, providers, health care payors and health care product manufacturers — in CER decision making.

In response, the Institute of Medicine recommended to Congress that new CER studies focus heavily on comparisons of entire treatment regimens rather than narrow comparisons of discrete technologies. Congress, in turn, largely heeded the concerns of the medical device industry and other stakeholders in the permanent CER initiative created by the final health care reform legislation (the Patient Protection and Affordable Care Act).

The newly expanded CER program will be directed by an independent entity, the Patient Centered Outcomes Research Institute (PCORI), with a 19-member board of governors comprising representatives from a wide array of stakeholder groups, including the medical technology industries. PCORI's operations and the research it commissions will be supported by surcharges levied on private health plans and self-insured employers.

One of the first orders of business for PCORI will be to constitute a committee on methodologies that will report back within 18 months on a plan to support the transparent development of appropriate CER methodologies. Congress forbade the Centers for Medicare and Medicaid Services from utilizing CER studies as the sole grounds for coverage and reimbursement decisions and otherwise urged federal agencies to focus on studies of clinical effectiveness, not cost-effectiveness.

Industry's concerns are not entirely allayed, of course. Industry can still expect to see studies of comparative cost-effectiveness from the National Institutes of Health, which has sponsored such studies for years. And while PCORI will not link CER studies to coverage and reimbursement decisions on its own authority, new federally sponsored CER studies will inevitably influence payor decisions, perhaps through decisions on tiered reimbursements or on pay-for-performance bonus payments. The impact of CER studies on payment policy may become more apparent even before PCORI is fully operational, as CER studies financed by the initial US$1.1 billion in American Recovery and Reinvestment Act funding are completed and released to the public.

The medical device industry will continue to monitor the release of CER studies, but much of its attention will be focused on the start-up of PCORI. Key decisions await, such as the selection of an executive director for PCORI, the hiring of staff and the adoption of procedures for prioritizing research topics and commissioning studies. Also still unknown is the shape of PCORI's interaction with the Agency for Healthcare Research and Quality (AHRQ), which is charged with disseminating CER studies and which continues to operate the Effective Health Care program — the CER program initiated with passage of the 2003 Medicare Modernization Act.

These key decisions will determine the long-term impact of CER on medical device development, approval and marketing.

An early benchmark for developers of health care technology (drugs and devices) will be whether the priorities enunciated by PCORI match the priorities envisioned by the Institute of Medicine, which, as noted, favors research on entire treatment regimens, as well as on disease states and conditions affecting broad swaths of the US population.

It will take time for PCORI to commission a body of research substantial enough to significantly influence medical care in the US, or to craft a dissemination strategy that will help to expedite the considerable body of existing medical research that is piling up on the desks of clinicians throughout the health care system. PCORI, AHRQ and the National Institutes of Health must weather several appropriation cycles in Congress before the new CER program begins to significantly influence medical practice in the US. And to reach that point, the program must survive the continuing controversy and political instability that swirls around health care reform.

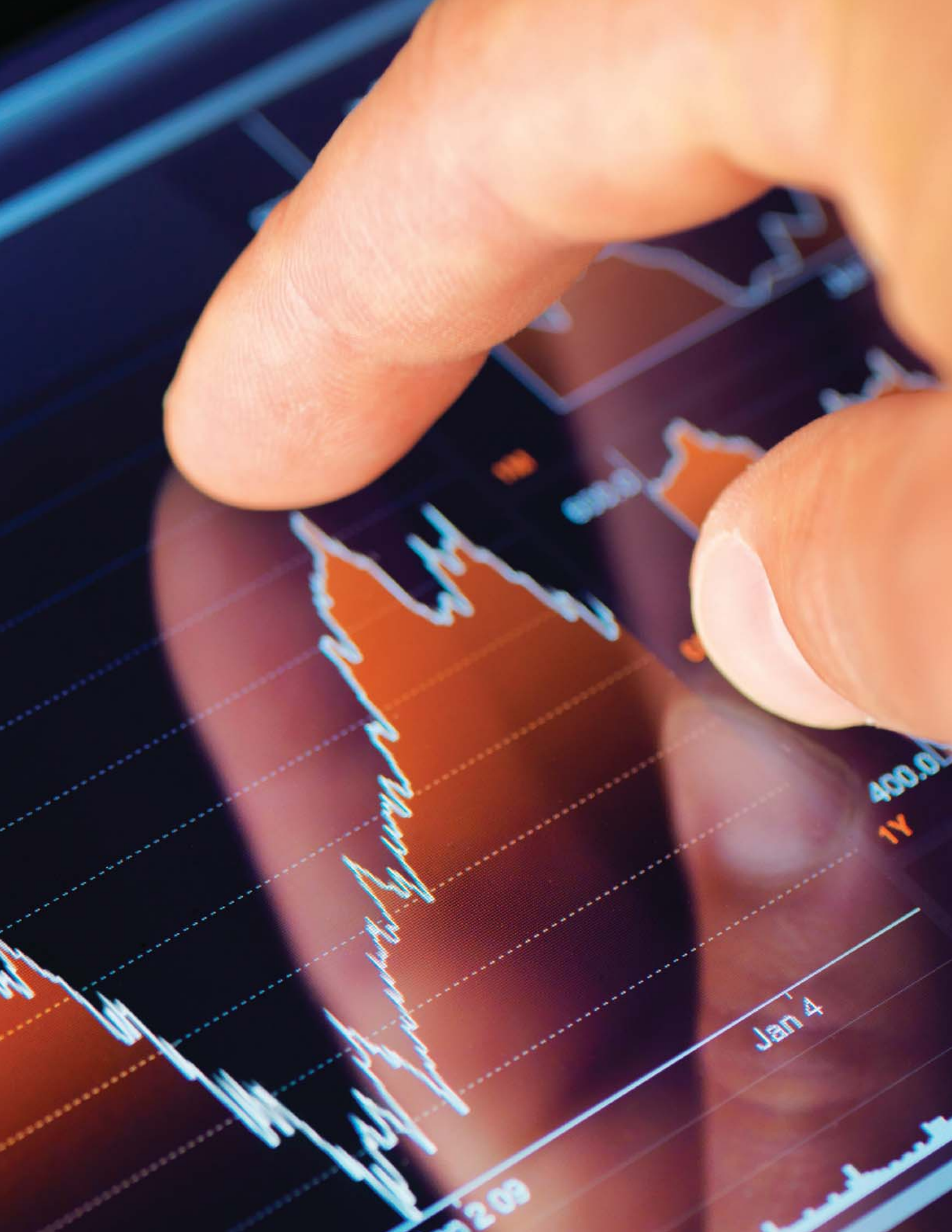
As Teresa Lee, Senior Vice President of AdvaMed, put it to the New England Healthcare Institute, "We are mostly in a waiting game right now." The Comptroller General of the US just appointed members of the PCORI board of governors in September 2010 and the medical device industry has two representatives on the board.

Industry leaders also hope that the PCORI board will take note of some of the unique challenges in medical device development as it establishes its priorities and its standards for CER studies. For example, medical devices are typically designed, redesigned and improved through iterative or incremental steps. CER studies commissioned at one point in time may not capture the impact of successive improvements to a device. The medical device industry would like to see PCORI acknowledge this and other aspects of the technology development cycle.

Issues of value in health care technology, including issues of how the health care system should or should not reward value, will continue to preoccupy the medical device industry as the new CER program moves forward. At its best, comparative research will identify which technologies work best for specific patients or patient populations under various sets of circumstances. The industry fears CER studies that lead to one-size-fits-all medical treatments, but it will welcome studies that make a strong scientific case for well-defined applications of specific medical technologies or overall protocols of care.

Robust CER studies may prove to be necessary, but not sufficient, to push the health care system toward greater recognition and reward of highly valuable innovation. Fundamental payment reform will probably be necessary for that to happen, but a well-managed CER program should be a useful step forward. ▶

Industry performance


400.0
1Y
Jan 4

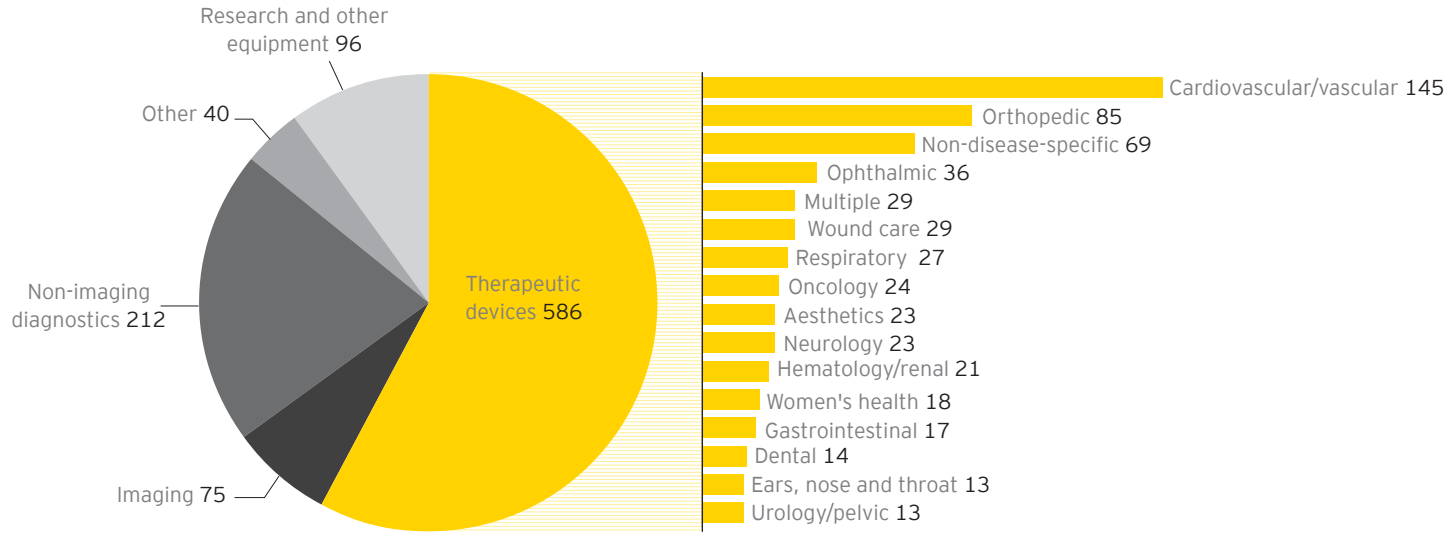
Industry segmentation

A diverse industry

As of 1 January 2010, there were 1,793 medical technology companies (for the definition of a medical technology company, please go to page 87) tracked by this publication. Of these, 441 (25% of the total companies) were publicly traded. This list of 441 companies largely consisted of pure-play medtech companies, but also included 22 conglomerates (14 in the US, 8 in Europe) that derived a significant amount of their total revenue from medtech products. In addition to the public companies, there were also 1,352 VC-backed companies, of which 738 (55%) were based in the US and 614 (45%) were headquartered in Europe.

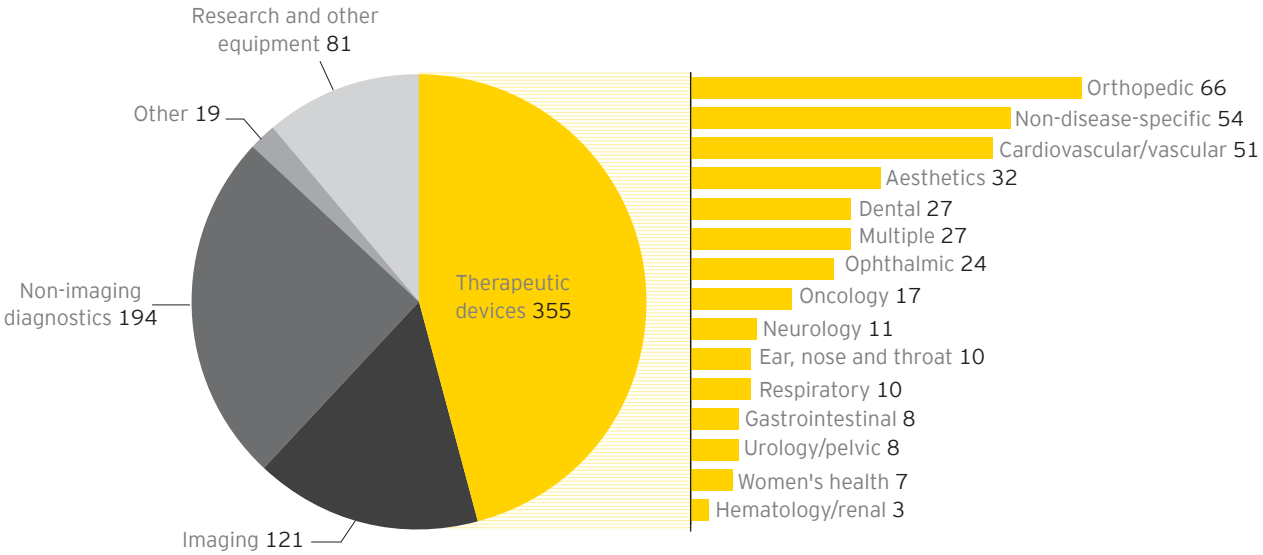
The geographic distribution of the medtech industry is similarly concentrated. Of the 1,023 medtechs in the United States (including 14 conglomerates), 51% were headquartered in one of three states – California, Massachusetts or Minnesota. Similar to the geographic concentration within the US, 56% of the 770 public and venture-backed European medtechs were headquartered in just three countries – the United Kingdom, Israel and Germany. Along with France and Sweden, these five countries accounted for 76% of all European companies. ▶

US public and VC-backed private companies by segment, 2009



Source: Ernst & Young
Chart does not include 14 conglomerate companies.

European public and VC-backed private companies by segment, 2009



Source: Ernst & Young

Selected 2009 US medical technology non-conglomerate, public company financial highlights by region (US$m, percent change over 2008)

Region	Number of public companies	Market capitalization 30 June 10	Revenue	R&D	Net income (loss)	Cash and equivalents	Total assets
Massachusetts	39	$77,075	$40,930	$2,606	$(1,039)	$6,883	$88,521
	(5%)	*3%*	*1%*	*5%*	*(468%)*	*10%*	*1%*
Minnesota	21	$59,389	$21,180	$2,138	$3,143	$2,695	$33,510
	0%	*0%*	*8%*	*5%*	*36%*	*17%*	*8%*
Southern California	37	$34,074	$15,383	$1,425	$1,329	$4,213	$30,009
	(12%)	*16%*	*17%*	*22%*	*32%*	*27%*	*8%*
Northern California	33	$29,446	$7,975	$816	$505	$3,514	$10,650
	(11%)	*57%*	*6%*	*(2%)*	*359%*	*27%*	*12%*
New Jersey	15	$24,649	$10,744	$629	$1,746	$2,728	$13,553
		(4%)	*1%*	*4%*	*13%*	*47%*	*12%*
Indiana	3	$8,221	$5,848	$205	$33	$969	$9,456
	0%	*302%*	*(3%)*	*7%*	*(66%)*	*118%*	*1%*
Michigan	3	$8,220	$6,828	$347	$1,109	$3,032	$9,207
	0%	*202%*	*0%*	*(7%)*	*(4%)*	*34%*	*19%*
New York	23	$4,259	$2,608	$157	$8	$462	$4,316
	0%	*25%*	*(5%)*	*(4%)*	*(84%)*	*13%*	*(2%)*
Texas	12	$5,401	$2,874	$172	$290	$519	$4,172
	0%	*24%*	*6%*	*11%*	*3,078%*	*(8%)*	*0%*

Source: Ernst & Young and company financial statement data
Market capitalization percentage change is over 30 June 2009.

Selected 2009 European medical technology non-conglomerate, public company financial highlights by country (€m, percent change over 2008)

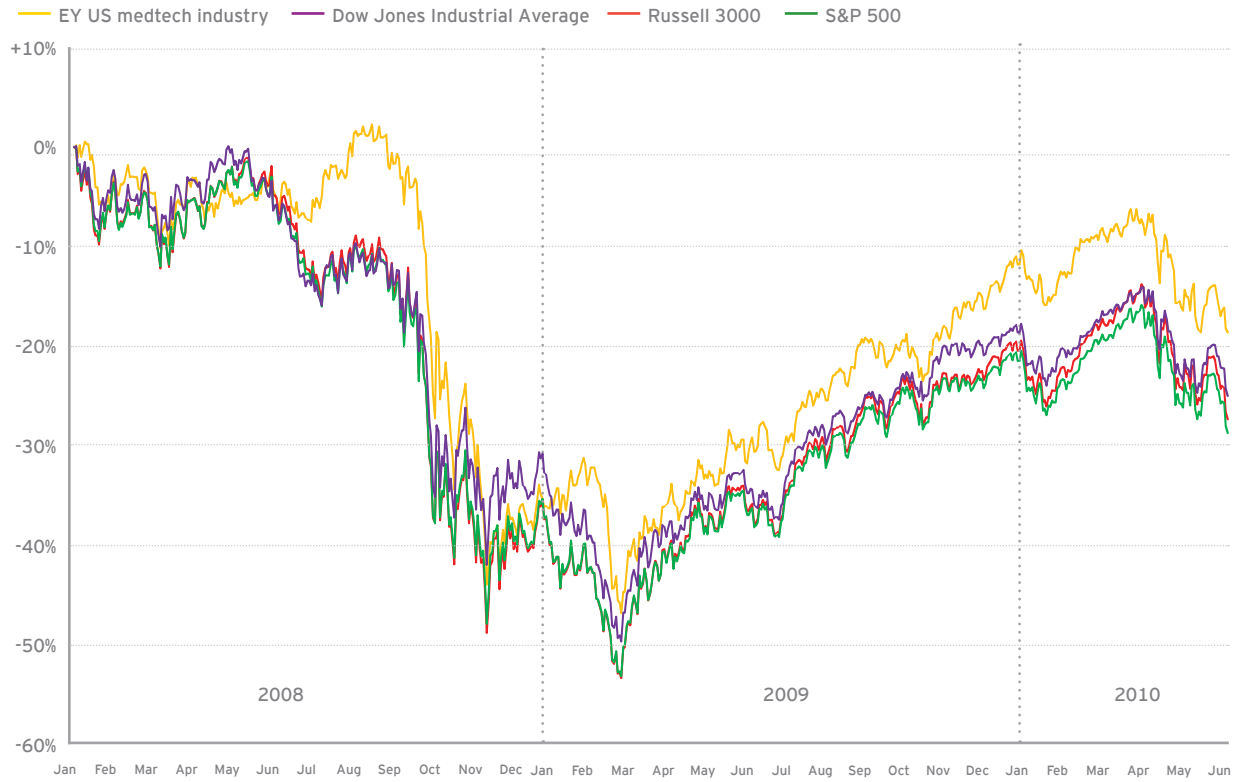
Country	Number of public companies	Market capitalization 30 June 10	Revenue	R&D	Net income (loss)	Cash and equivalents	Total assets
Switzerland	11	€47,624	€4,498	€275	€1,168	€594	€2,809
	0%	*94%*	*7%*	*10%*	*13%*	*(1%)*	*(6%)*
Germany	22	€32,237	€13,891	€293	€898	€385	€20,103
	(4%)	*81%*	*12%*	*10%*	*17%*	*136%*	*6%*
France	14	€13,276	€5,672	€358	€601	€540	€6,932
	8%	*27%*	*7%*	*7%*	*4%*	*15%*	*4%*
UK	25	€9,555	€3,540	€164	€335	€219	€4,003
	0%	*38%*	*2%*	*(8%)*	*49%*	*28%*	*4%*
Sweden	25	€5,539	€3,111	€135	€284	€344	€4,862
	0%	*50%*	*8%*	*(4%)*	*41%*	*64%*	*(57%)*
Israel	25	€1,025	€337	€42	€32	€94	€609
	0%	*199%*	*(5%)*	*(5%)*	*(124%)*	*17%*	*5%*

Source: Ernst & Young and company financial statement data
Market capitalization percentage change is over 30 June 2009.

Stock market performance

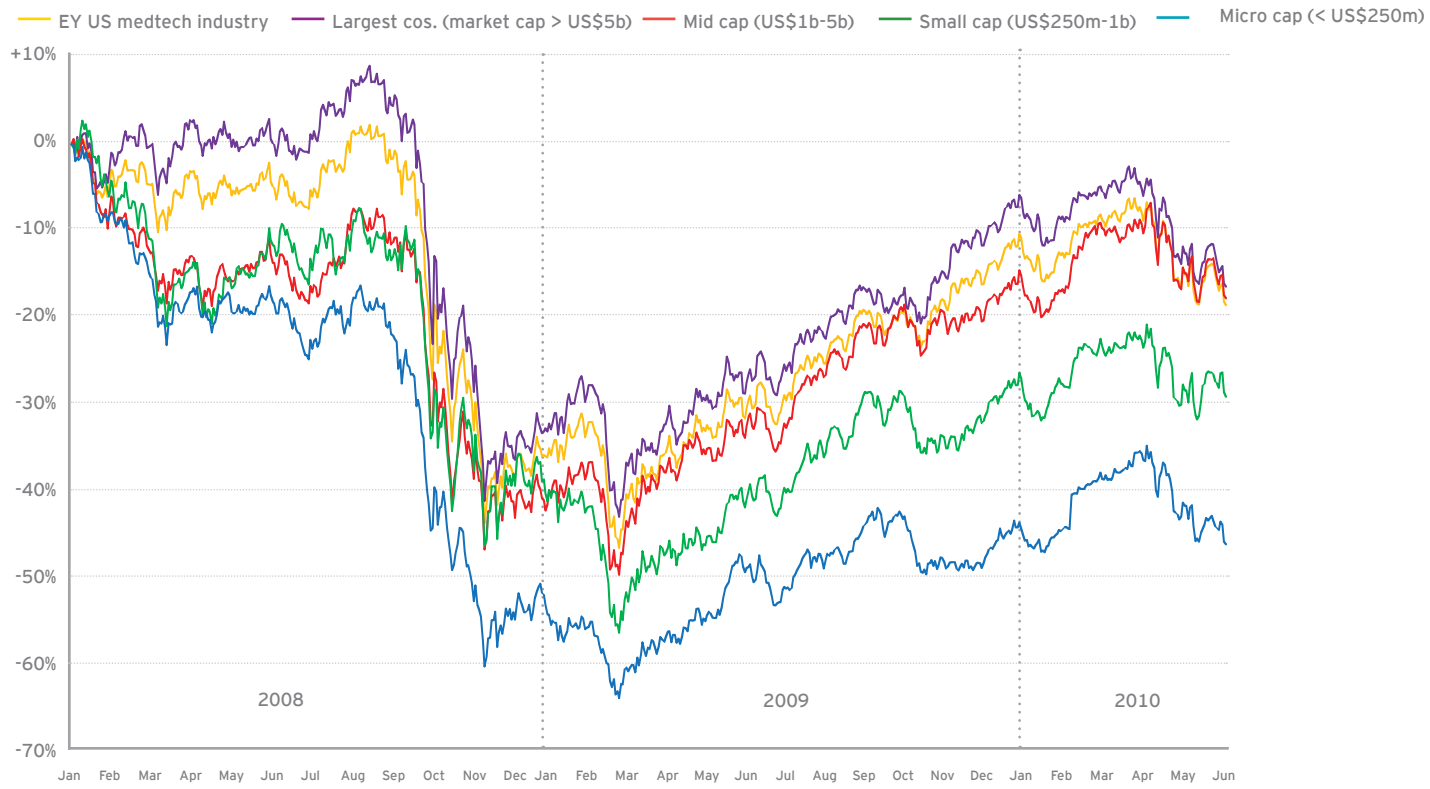
In both the US and Europe, medtech outpaced the overall market ...

US market capitalization, 2008–H1 2010



... while the gap between small and large companies continued to grow

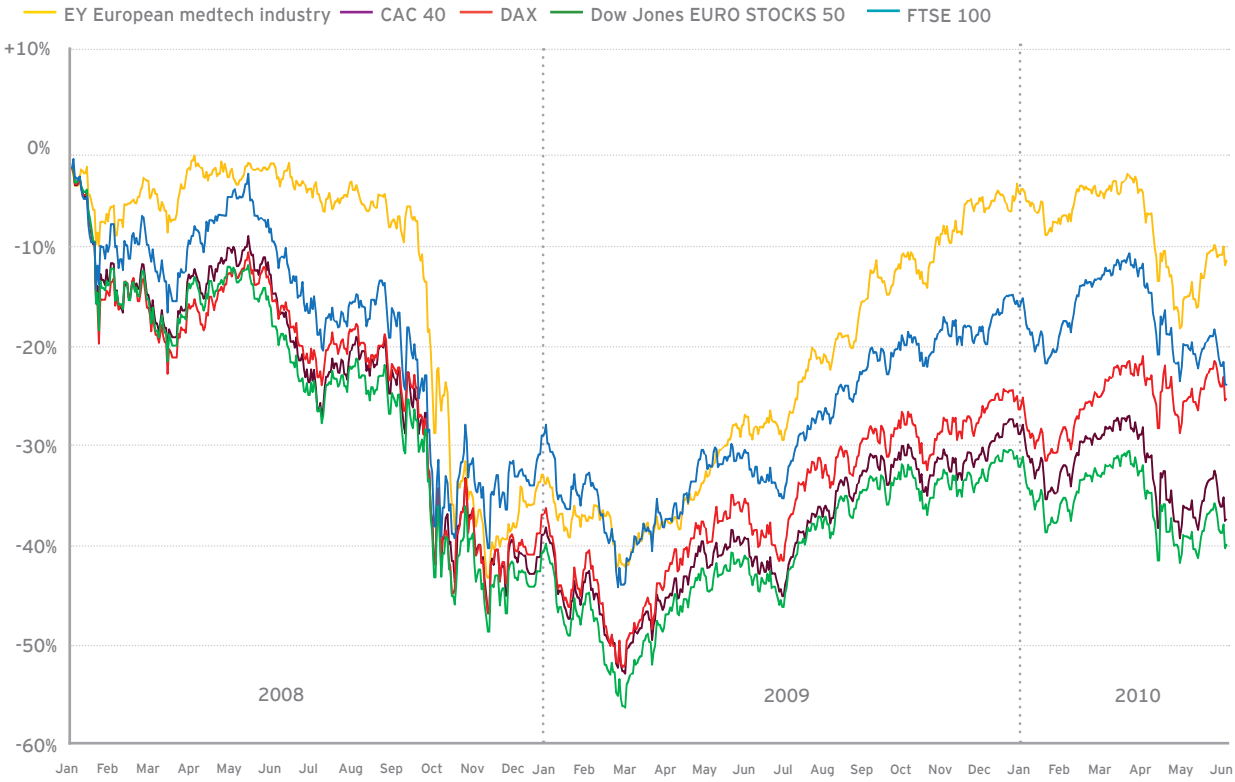
US market capitalization by size, 2008–H1 2010



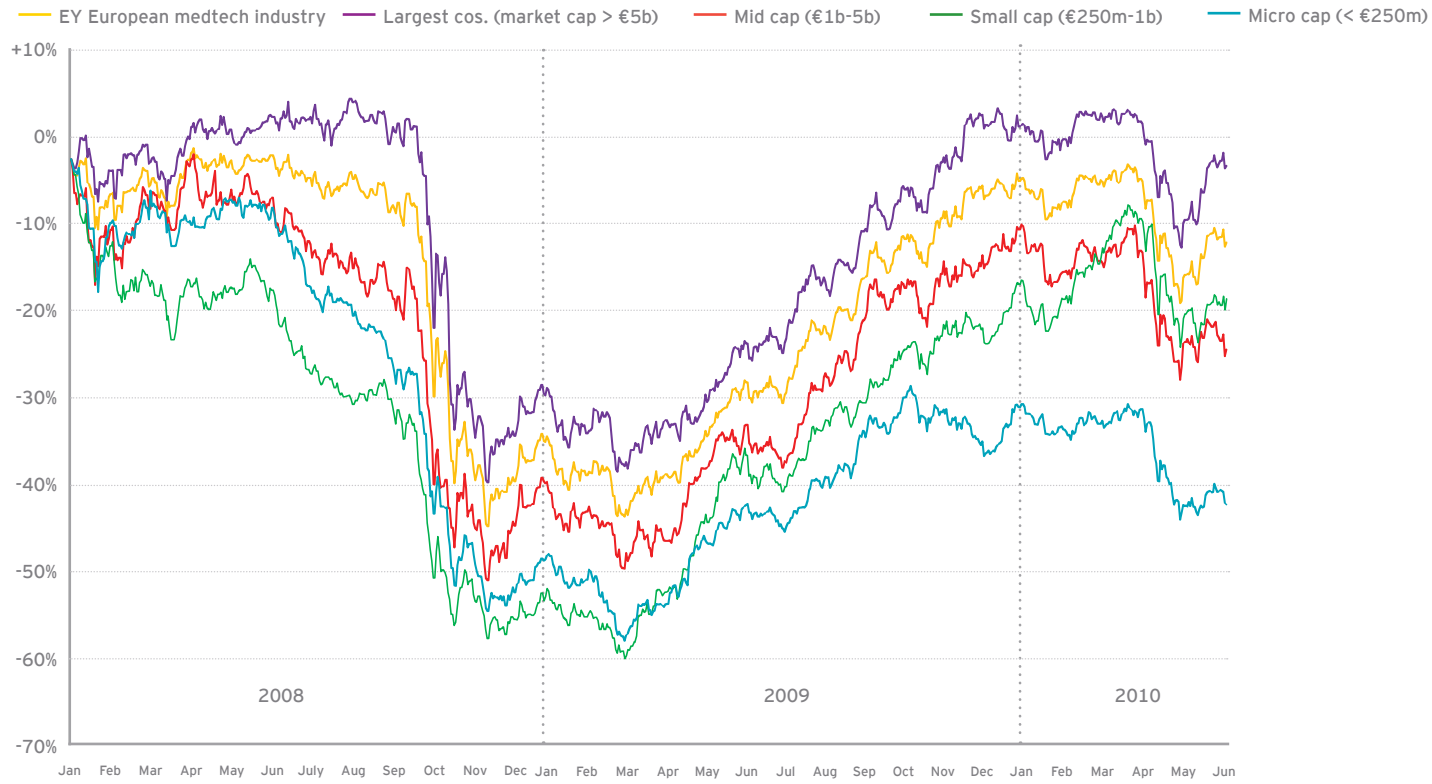
Source: Ernst & Young and Capital IQ

"EY US medtech industry" and "EY European medtech industry" represent the aggregate market cap of all US and European public medtech companies as defined by Ernst & Young.

European market capitalization, 2008–H1 2010



European market capitalization by size, 2008–H1 2010



Financial results

The (medtech) world is flat

With strong operating margins, medtech companies have historically delivered profits by focusing on top-line growth. This changed dramatically in 2009, when the challenging economic climate brought a heightened focus on improving bottom-line performance through more efficient operations.

The combined revenues of US and European publicly traded medtech companies were practically unchanged in 2009 relative to 2008, increasing by a miniscule 0.3% to US$294.1 billion. The change in revenues achieved by non-conglomerates (up 0.9%) and conglomerates (down 0.7%) was similarly flat. This clearly fell short of the 11% growth attained in 2008, but given the difficulties in the overall economy and many other industries, it wasn't very surprising.

Whereas conglomerates report revenue for their medtech divisions, they do not typically report other financial results, such as R&D expenditures or net income. The remainder of this section will therefore focus primarily on the results of pure-play medtech companies.

US and European medtechs collectively grew their net income by 10.8% to US$13.2 billion, with Europe adding 29% (22% when converted into US dollars) to the bottom line and the US recording a 4.3% increase. Europe's top-line growth and a reduction of one-time charges in the US were largely responsible for the industry's increased operating income. Two main items of expenditure — headcount and R&D — actually increased slightly. However, the headcount numbers are considerably skewed by the addition of 15,000 employees from CareFusion (which was spun out of Cardinal

Medical technology at a glance – 2009

US$m, data for non-conglomerates except where indicated

Public company data

	Combined	Growth	US	US growth	Europe	Europe growth
Revenues (all companies)	$294,068	0.3%	$196,693	-0.1%	$97,375	1.1%
Non-conglomerates	$181,108	0.9%	$127,849	0.3%	$53,259	2.4%
Conglomerates	$112,960	-0.7%	$ 68,844	-0.9%	$44,116	-0.4%
R&D expense	$ 11,380	1.3%	$ 9,122	2.2%	$ 2,258	-2.1%
Net income (loss)	$ 13,179	10.8%	$ 7,879	4.3%	$ 5,300	22.0%
Cash & equivalents and short-term investments	$ 34,569	15.7%	$ 27,858	18.0%	$ 6,711	8.1%
Number of employees	712,508	1.8%	456,137	2.8%	256,371	0.2%
Market capitalization	$479,004	35.1%	$318,217	34.2%	$160,787	36.9%

Number of companies

	Combined	Growth	US	US growth	Europe	Europe growth
Public companies	441	-5.8%	285	-5.0%	156	-7.1%
VC-backed companies	1,352	n/a	738	n/a	614	n/a

Source: Ernst & Young. Growth is relative to 2008. Number of public companies includes conglomerate companies.
Prior year amounts (except employees) are restated for the impact of CareFusion's spin out from Cardinal Health (which was included in the conglomerate category in 2008).

Health in September 2009) to our non-conglomerate company list. Barring CareFusion's addition, total headcount would have *declined* by roughly 0.5% instead of increasing by 1.8%.

US financial performance

The revenues of US publicly traded medical technology companies fell short of the US$200 billion mark in 2009, sliding to US$196.7 billion, a 0.1% decrease from 2008. This slight year-over-year contraction comes on the heels of an 11.2% growth rate in 2008 and is the first time the US industry has experienced a revenue decline since at least 2004. Unlike 2008, when every US conglomerate experienced positive revenue growth, only half of them saw growth in 2009. Overall, conglomerate top-line growth decreased slightly to US$68.8 billion in 2009. Of the conglomerates, Allergan and GE Healthcare suffered the biggest drops in revenue. Allergan attributed its revenue drop to a strong US dollar and a decline in consumer (elective, aesthetic) spending due to the negative economic environment, while GE explained that the decrease in revenues was the result of generally weak global economic conditions and continued uncertainty in the health care markets, resulting in reduced appetite for large capital purchases. On the other hand, Genzyme, Corning and Kimberly-Clark all enjoyed year-over-year double-digit growth rates. Genzyme's growth was fueled by the approval of its Synvisc-One osteoarthritis product, while Kimberly-Clark's increase was the result of its I-Flow acquisition, as well as increased demand for its face masks due to the H1N1 influenza crisis. Corning Life Sciences' improved net sales reflected its acquisition of lab equipment company Axygen.

In 2009, non-conglomerate revenues crept up 0.3% – well below the 12.6% growth achieved the year before, but still respectable given the overall economic environment and unfavorable foreign

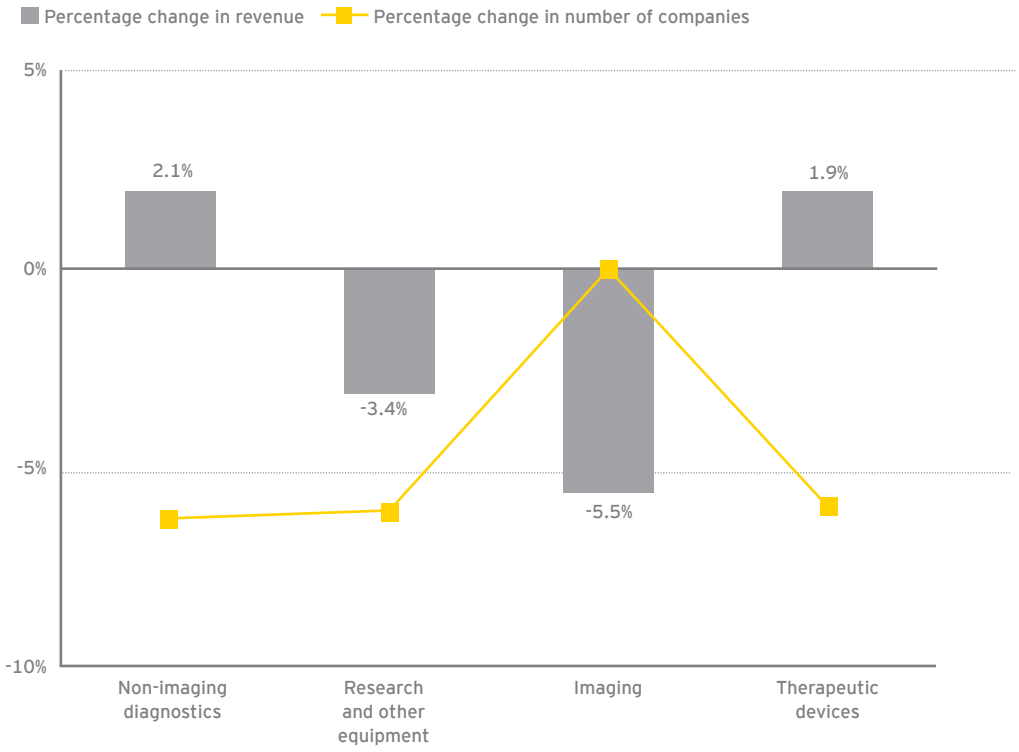
exchange rates. Only 52% of companies saw revenues increase during the year, down from 67% seen in 2008.

While we estimate that foreign-exchange tailwinds helped to drive nearly half of the 12.6% revenue growth in 2008, a strong US dollar in the first half of 2009 negatively impacted American companies selling overseas. For example, at the 10 largest US non-conglomerates by sales, approximately 2.2% (US$1.6 billion in total) of revenue was lost to exchange rates.

A year after all four product groups achieved at least 9% revenue growth, only non-imaging diagnostics and therapeutic devices experienced growth in 2009, and that too at much reduced levels. Non-imaging diagnostics saw the biggest percentage revenue increase (2.1% or US$249 million) in 2009, which was solely the result of Alere's health management and professional diagnostics-related acquisitions. On the other hand, the imaging segment's revenues fell 5.5% (US$124 million) from 2008. Imaging's decline was largely the result of the removal of Emageon from the numbers (after the company was acquired by AMICAS; AMICAS itself has since been acquired by Merge Healthcare) and a decrease in sales volume at the Medical Systems Group within Del Global Technologies.

Therapeutic device revenues inched up 1.9% to US$76.6 billion in 2009, as 8 of the 15 disease categories saw top-line increases. Led by Haemonetics and diabetes management company, Insulet, hematology/renal jumped 16% and took the honors as the fastest-growing segment in therapeutic devices. The three largest disease segments by revenue – cardiovascular/vascular, orthopedic and multiple – all saw their top lines increase. Strong organic growth at Edwards LifeSciences and St. Jude Medical resulted in an increase of 5% in cardiovascular/vascular's revenues, while Medtronic and Kinetic Concepts helped drive the 6% improvement in the multiple segment. On the negative side, the acquisition of Advanced Medical Optics (AMO) was largely responsible for a 50% decline in

US revenue growth by product group, 2008–09



Source: Ernst & Young

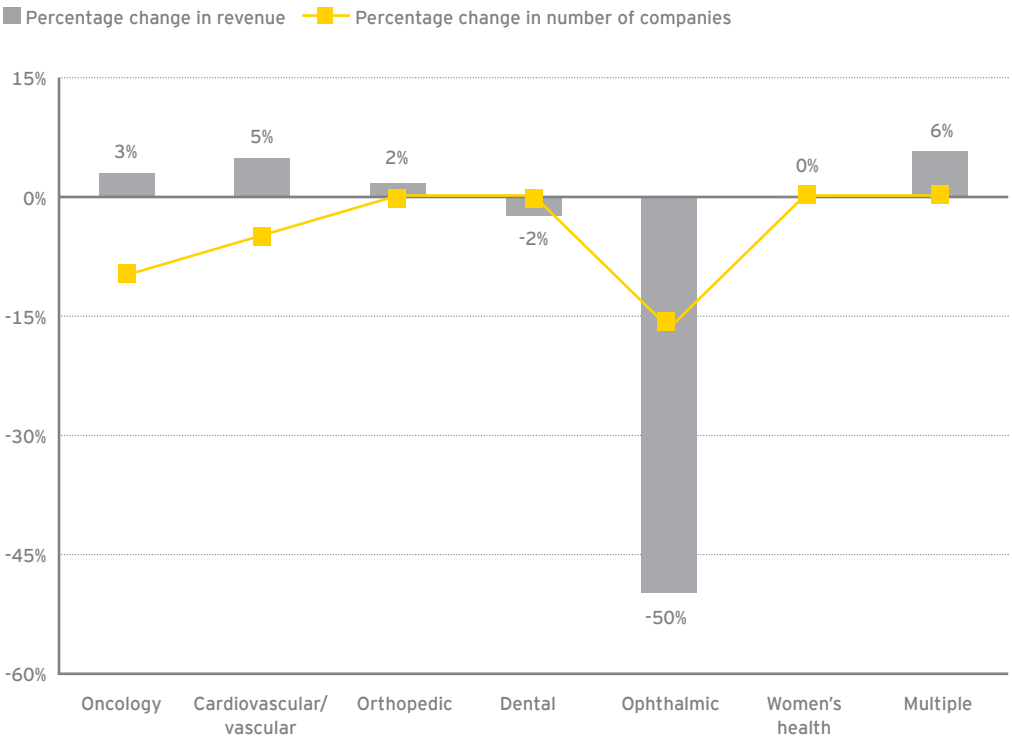
ophthalmic revenue, while a string of acquisitions and a slowdown in discretionary spending resulted in a 49% drop in aesthetics. Barring AMO's acquisition, ophthalmic revenue would have actually increased 3%.

Through the first six months of 2010, US medtech revenues surged 7% over the same period in 2009. Non-conglomerate revenues expanded 6% year-over-year as all five product groups experienced top-line growth, with non-imaging diagnostics leading the way with an increase of 9%. Therapeutic device companies saw their aggregate revenues expand 6% year-over-year, with the orthopedic, multiple and dental segments all experiencing healthy growth. These positive figures may indicate that the freeze on capital spending by hospitals is beginning to thaw, while patients may also be moving forward with procedures they had deferred during the economic downturn. However, it appears that the elective, self-pay market has still to turn the corner as aesthetic revenues were off by nearly 8% during the first six months. Conglomerates as a whole were up 8% as 12 of the 14 medtech divisions grew their top lines, 7 of them achieving double-digit gains. Johnson & Johnson, Danaher and Abbott drove the largest dollar gains within the conglomerates.

Providers putting the squeeze on medtechs

In last year's *Pulse* report, we discussed how the financial crisis had negatively affected private providers and government health systems. Private hospitals in the US were particularly hard hit by a host of challenges that included declines in admissions, reductions in elective and out-of-pocket procedures, increases in uncompensated care, tighter Medicare and Medicaid reimbursement, a lack of investment income and reduced charitable donations.

US revenue growth by selected disease category therapeutic devices, 2008–09



Source: Ernst & Young

Fast forward a year to the summer of 2010 and it's obvious that the recession has continued to take a toll on providers. According to an April 2010 American Hospital Association (AHA) survey, 70% of hospitals reported lower patient volumes and 72% reported reductions in elective procedures. As unemployment hovered near 10% in the US, hospitals continued to see increased enrollment in programs such as Medicaid, and nearly 9 out of 10 hospitals reported an increase in uncompensated care. With three-quarters of hospitals reporting reduced operating margins, others remained hampered by a lack of liquidity and access to the capital markets. As a result, many hospitals are understandably cautious about their own financial health and continued to rein in or delay many expenditures, including investments to update facilities and equipment. While these cutbacks affected all product classes, from low-end to premium products, capital equipment faced the greatest obstacles. The AHA reported that hospitals' capital expenditures for products such as MRIs, robotic surgical systems and other hospital equipment would experience lower growth rates or even declines in revenue for the foreseeable future. Of course, hospitals cannot defer capital spending indefinitely without potentially weakening their competitive positions and impacting quality of care.

To further offset decreases in reimbursement and tighter margins, hospitals have been finding new ways to reduce medtech-related costs. In addition to exerting pressure through Group Purchasing Organizations (GPOs) — a long-standing means of negotiating lower prices with medtech manufacturers — hospitals are also limiting the number of vendors and tying physician compensation to the use of preferred products.

The impact of the US medical device excise tax

The 2.3% excise tax on the US revenue of medical device manufacturers won't take effect until 1 January 2013, leaving some time for the industry to try to address the most burdensome impacts of the tax — especially those affecting emerging companies. However, in order to understand the pending changes, we estimated the approximate impact of the tax at an industry level, had the tax been imposed on 2009 revenues. As the excise tax rules are complicated, and will be subject to the issuance of further regulations, the actual impact by company will vary.

As of December 2009, there were 98 profitable US non-conglomerate public medtechs. As a result of the excise tax, these companies would have paid, on an after-tax basis, approximately US$973 million in 2009 (of which 88% is driven by the top 10 medtechs by revenue), which would have decreased their net income by 7.5%. Surprisingly, only 4 of the 98 companies would have seen their bottom lines turn red. The 96 medtech companies that had revenue but were not profitable would have been subjected to the full 2.3% of the tax and would have been responsible for paying approximately US$146 million — a 4.7% increase in their net loss.

Larger companies will obviously shoulder the lion's share of the aggregate US$2 billion tax each year, but they are better equipped to absorb its impact, and they also earn a large percentage of their sales from overseas sales that aren't subject to the tax. It is the small public and venture-backed firms that will be disproportionately impacted. These companies often have most of their sales in the US, are heavily invested in R&D and tend to have lower operating margins as they invest in commercial infrastructure. And in a time of extraordinary financial and regulatory pressures, the tax will delay profitability for some smaller players, increasing the strain on investors. (For a more detailed examination of the excise tax, see "A closer look" by Chris Ohmes on page 40.)

Other US financial indicators

While US medtech companies struggled to accelerate top-line growth in 2009, their net incomes climbed more than 4%, an improvement on the nearly 8% decrease in the prior year. More than two-thirds of US public medtech companies improved their bottom lines. US net income reached US$7.9 billion in 2009 on the back of company cost-containment efforts, a change in accounting rules for acquisitions, and the absence of some special one-time

charges that hit in 2008 — in particular, Boston Scientific's US$2.8 billion write-down of goodwill and intangible assets related to the 2006 Guidant acquisition. Boston Scientific added US$1 billion to its net income in 2009 though the company was still in the red by more than US$1 billion overall due to various litigation-related charges. Other companies that saw substantially improved net income included St. Jude Medical (up 120% due to US$400 million in after-tax charges in 2008), ev3 (up 113% due to $288.8 million in non-cash, asset impairment charges in 2008; since purchased by Covidien), and Affymetrix (up 92% due to US$239 million of goodwill impairment charges in 2008). Conversely, Hologic, Hill-Rom and Covidien experienced considerable deterioration to their net incomes. In the case of Hologic and Hill-Rom, the decreases were primarily due to substantial write-downs of goodwill and other intangible assets, while a combination of restructuring charges and legal settlements drove much of Covidien's decrease.

Overall profitability in 2009 was also favorably affected by the change in accounting rules for the treatment of in-process R&D (IPR&D). Acquisitions by US medtech companies have typically resulted in sizeable charges for acquired IPR&D — the estimated fair value assigned to ongoing R&D projects acquired in a business combination. Given the active deal environment in recent years, the US industry's profitability has been lowered every year by these charges. However, in 2009, when the treatment of acquired IPR&D changed, US medtechs no longer immediately expensed IPR&D but rather capitalized the cost as an asset, eventually amortizing the assigned value to expense. So while US non-conglomerates grew their net incomes by US$324 million in 2009, we estimate that roughly US$850 million of that figure was the result of this accounting change. Barring these changes, net incomes would have actually fallen by more than US$500 million between 2008 and 2009.

Through the first six months of 2010, net income was up 62% (to US$4.8 billion) compared to the same period the year before. However, barring several one-time charges and write-downs, net income would have gone up roughly 16% year-over-year on a normalized basis.

Despite general belt-tightening across the industry, R&D grew by 2.2% to US$9.1 billion — its highest level in at least the past six years. R&D expenditures continued to increase during the first half of 2010 as US medtechs spent 3.3% more than they did during the same period in 2009.

While US unemployment hovered stubbornly around 10%, the headcount of non-conglomerate medtechs remained virtually flat. While the US industry's headcount increased by 12,000 jobs in 2009, as we mentioned earlier, this figure is distorted by a 15,000 employee addition from the inclusion of CareFusion to our non-conglomerate company list. Of course, these figures don't include headcount reductions that may have occurred within conglomerates or the VC-backed and privately held medtechs, the latter of which may have been disproportionately impacted by a more constrained financing environment.

After two years of declines, company cash holdings skyrocketed 18% to nearly US$27.9 billion in 2009, the highest level in at least six years. At the end of 2009, 56% of medtechs had increased their cash reserves, which was well above the 40% that did the same in 2008. Of course, conservative cash positions were not unique to the medtech industry, as larger companies across many industries sought to preserve cash in an uncertain economic climate. As confidence returns, it will be interesting to observe how much of this cash is used to fund acquisitions.

The US industry's aggregate public company market capitalization also jumped, 34% year-over-year, but was still down by more than 16% from the end of 2007. After plummeting with the overall market in the fourth quarter of 2008, US medtechs as a whole have continued to outpace the Dow Jones Industrial Average, the Russell 3000 and the S&P 500 indices. However, the growing divergence between large-cap and micro-cap medtech valuations has been alarming, as the latter group's overall performance has trailed the former's by a range of 20%–30% since the beginning of 2008. The lack of liquidity in small-cap stocks will often impact investor sentiment in times of uncertainty and is likely the reason behind this spread. In the first half of 2010, medtech stocks declined by 9% —

slightly below the broader markets but still up 22% since the end of 2008.

Among the product segments, only aesthetics and non-imaging diagnostics have experienced losses in public valuation between the end of 2008 and 30 June 2010, while imaging, oncology, and research and other equipment led medtech in growth. While medtech stocks have certainly rebounded from their lows in the fourth quarter of 2008, they are still well off their levels prior to the onset of the financial crisis. Since the end of 2007, only respiratory companies had increased their valuations by the halfway mark in 2010, with other segments, such as cardiovascular/vascular, orthopedic, dental and aesthetics, still attempting to rebound to their earlier valuations.

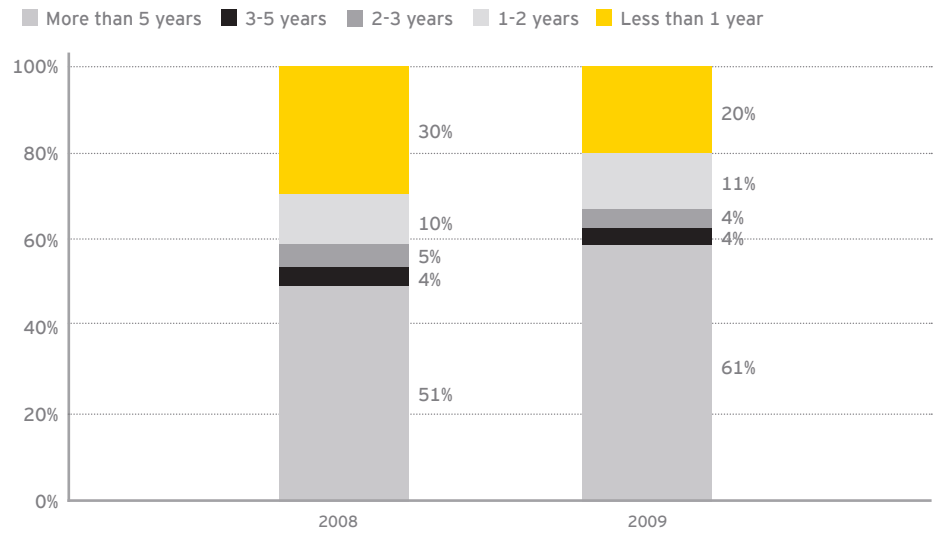
European financial performance

European public medtech companies increased their aggregate top line by 1.1% to €70.0 billion (US$97.4 billion) from 2008 to 2009. Unlike the US, where a stronger dollar slightly dampened revenues, a weaker euro against the dollar and other key currencies boosted many European medtech company top lines in 2009. According to multiple sources, this tailwind benefitted company revenues anywhere from 1% to 5%.

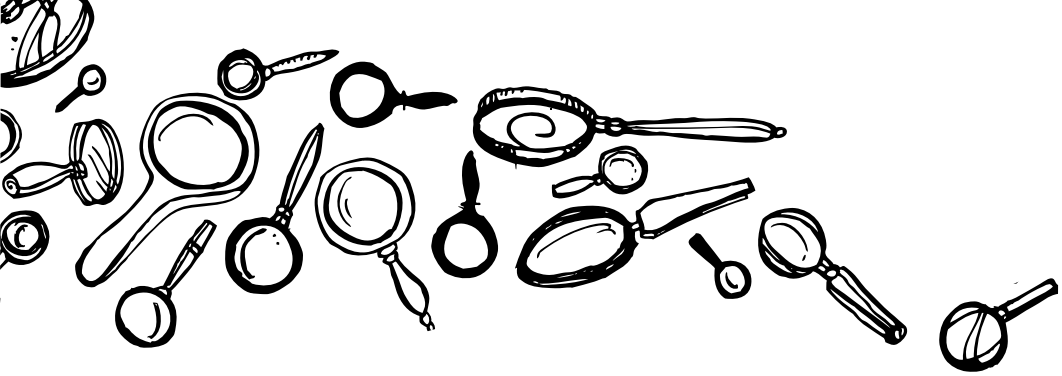
Non-conglomerates brought in 55% of total European revenue. Unlike their US-based counterparts, Europe's conglomerates also delivered positive growth figures – up 0.4% – with Switzerland's Roche and Germany's Dräger leading the pack and six of the eight companies increasing revenues. Roche's Diagnostics Division grew 9.5%, with all five of its divisional businesses experiencing organic growth, while Dräger Medical grew 7.7% based on higher volumes from multiple product areas. Unlike previous years, revenue growth for European conglomerates was not fueled by major acquisitions.

On the non-conglomerate side, all four product groups increased revenue in 2009, with imaging leading the way by adding 5% to its top line. The imaging segment's growth was primarily driven by Sweden-based Elekta's organic expansion within the field of image-guided radiation therapy and stereotactic radiosurgery. Therapeutic device companies increased revenues by 8% in 2009, with hematology/renal, ophthalmic and dermatology driving the largest amount of growth in euro terms. As Europe's only public hematology/renal firm, Fresenius Medical Care's strong organic and acquisition-driven growth drove expansion in the segment, while Alcon Surgical and France's Essilor International grew 10% and 5% respectively, to help speed the advance in ophthalmic revenue. Alcon, which was in the midst of being acquired by Novartis from Nestlé (the firm is headquartered in the US but included in our

US public medtech cash index



Source: Ernst & Young



A closer look

The uncertain incidence of the medical device excise tax

Chris Ohmes
Ernst & Young LLP

As part of health care reform, the US Congress adopted a new excise tax on domestic medical device sales. Merely creating the systems and procedures to ensure proper compliance with this new tax will be demanding, but determining how to respond to the tax will be even more complex. When implemented, the newly enacted medical device excise tax likely will result in substantial economic dislocations within the medical device manufacturing industry.

This new tax is to go into effect on 1 January 2013 and applies at a rate of 2.3% of sales. For purposes of this tax, medical device sales include sales, leases and rentals of medical devices for human use in the US. Imports also are subject to the tax. Export sales are exempt, as are sales for use in further manufacturing, but there is no broad sales-for-resale type of exemption. A retail exemption was adopted, but it applies only to eyeglasses, contact lenses and hearing aids until implementing regulations are adopted. The US Treasury Department is authorized to expand this exemption list to include device types generally purchased by the public at retail for an individual purchaser's use, but industry input will be necessary in order for Treasury to adopt any new rules.

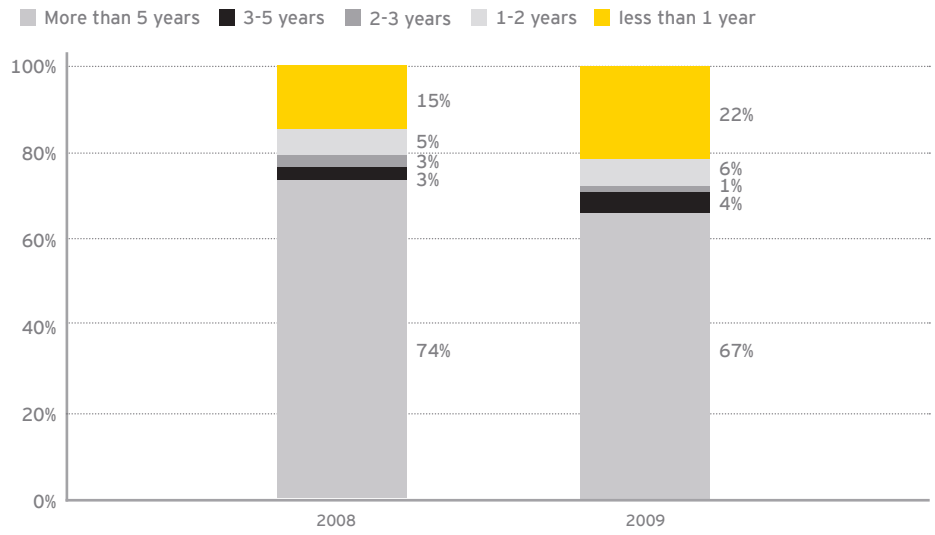
Given that almost half of all domestic medical device sales are associated with medical services paid for by Medicare and Medicaid, and that patients of either the Veterans Administration or the Department of Defense also are substantial users of medical devices, it is unlikely that the tax will merely pass through to customers. Indeed, it will be difficult to assess how much of this tax can be passed along to customers in the form of higher prices.

Faced with a possible residual liability for the tax, manufacturers may try to push the tax back onto their suppliers. Moreover, it is anticipated that companies will seek to unbundle products consisting of multiple components and to limit the definition of a medical device. For example, companies may seek to exclude a keyboard used to initiate the operation of a device from the definition of "medical device" subject to the tax. But even this response could become complicated as the act of unbundling some components to avoid federal excise tax may expose a previously exempt medical device to some state and local sales taxes.

Determining how to deal with previously taxed items also will be complex. For example, a company that fully manufactures its medical devices both within and outside the US will need to pay tax on the importation of devices manufactured offshore. This company will then, upon sale to the ultimate customer, need to ascertain whether it is selling a previously taxed imported device or an untaxed device.

As the 1 January 2013 effective date of the tax approaches, medical device manufacturers also may want to consider that this tax may simultaneously create tension with their customers and within their supply chains. ▶

European public medtech cash index



Source: Ernst & Young

European data because of its Swiss parent) grew revenue on the heels of strong global sales of its advanced intraocular lenses. Meanwhile, Essilor's growth came from a combination of factors, including organic and acquisition-led expansion of its lens business and positive currency effects.

European non-conglomerates slightly outpaced their US counterparts in revenue growth during the first six months of 2010. As in the US, all five product groups achieved top-line growth year-over-year, and the industry was paced by therapeutic devices' 11.6% increase. The expansion within therapeutic devices was largely driven by the ophthalmic, orthopedic and hematology/renal segments.

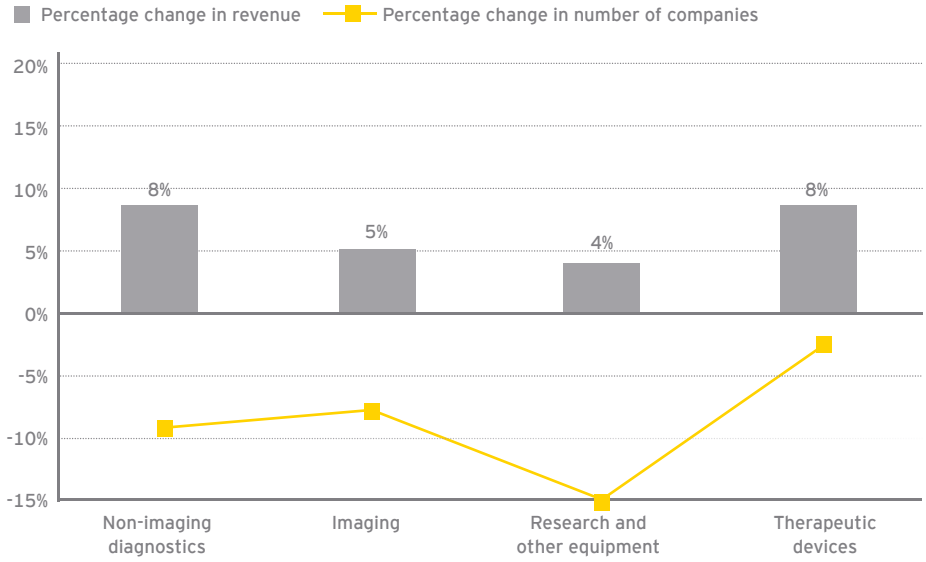
Top European revenue growth leaders in 2009 (by € growth)

Company	Growth (€m)	% growth
Fresenius Medical Care	€873	12%
Siemens Healthcare	€757	7%
Fresenius Kabi	€591	24%
Roche Diagnostics	€578	10%
Essilor International	€194	5%

Other European financial indicators

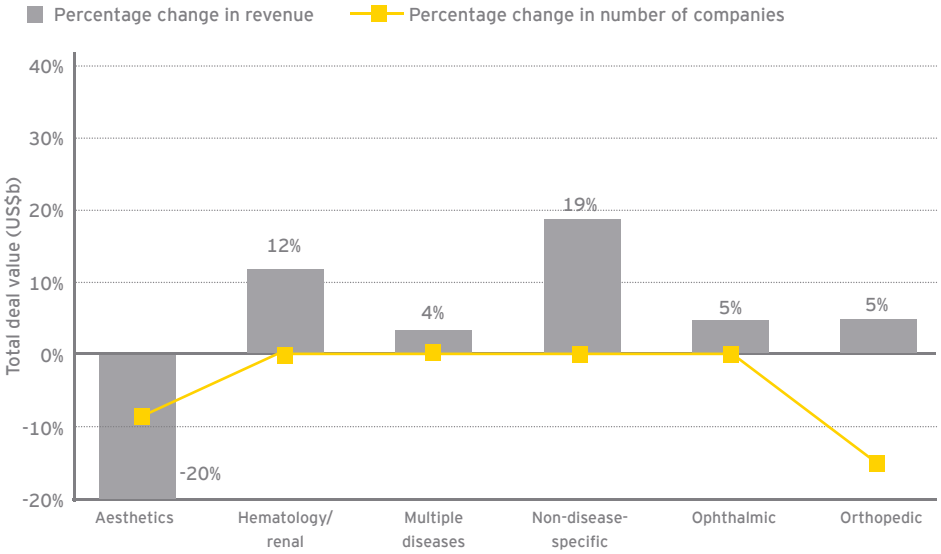
European non-conglomerates improved their bottom lines by more than 29% (22% in US dollars) in 2009. Sixty percent of European medtechs increased their net profits, with Straumann, Fresenius Medical Care and Smith & Nephew expanding their earnings the most. Alcon Surgical, Fresenius Medical Care and Essilor International alone accounted for 46% of all non-conglomerate net

European revenue growth by product group, 2008–09



Source: Ernst & Young

European revenue growth by disease category therapeutic devices, 2008–09



Source: Ernst & Young

income, and surprisingly, not a single public medtech in Europe lost more than €20 million (US$28 million) in 2009. Through this robust profit growth, European non-conglomerates managed to expand R&D spending by 3.6% (-2.1% when converted to US dollars) while also adding minimally to their overall headcount. And in the US, European medtech stocks have outpaced the broader indices since the beginning of 2008. However, the gap between the large and micro-cap companies' performances has been upwards of 30%. Tight capital markets, the lack of liquidity and increasing government pricing pressures are just a few concerns that have likely depressed small-company valuations.

Top European net income leaders in 2009 (by € growth)

Company	Growth (€m)	% growth
Fresenius Medical Care	€641	15%
Essilor International	€394	3%
Smith & Nephew	€340	5%
Sonova Holding	€188	13%
Getinge	€180	12%

Austerity measures and late payments

While health care reform and FDA issues have topped the list of concerns for medtechs operating in the US, those that sell their products in Europe have also had a new set of issues with which to concern themselves. As the global recession has negatively impacted government tax receipts, many European governments are faced with significant deficits. Medtech companies with exposure to European markets should be increasingly prepared for austerity-driven price cuts across the continent, particularly in markets with spiralling sovereign debt figures.

Though the announced health care price cuts in markets such as Greece, Italy and Spain have so far primarily focused on pharmaceuticals for fiscal savings, medtech products may also be targeted. So far, price cuts for drugs have ranged from 5% to more than 25%. Should similar cuts be implemented on medtech products, the business models of companies operating in specific European countries will be directly impacted as governments often account for a large proportion of medtech sales.

According to Eucomed, there are also €11 billion (US$15 billion) worth of unpaid invoices for medtech products across Europe. This is especially troubling since 60% of payments that are due come from the public sector, and some European countries are facing fiscal challenges. While some countries, such as Germany, will normally make payments within 30 to 60 days, others, such as Greece and Italy, can take upwards of 600 to 800 days. While the European Parliament is attempting to address late payments, there are a number of significant hurdles that need to be cleared, and the situation is unlikely to improve in the near term. As a result, companies of all sizes — but particularly modest-sized concerns — will need to focus on the working-capital challenges this raises.

Outlook

The medtech industry should continue to gain more clarity on its near-term financial prospects throughout the remainder of 2010 and into 2011. As the global economy continues to slowly grow out of the recession, we anticipate that business conditions will improve for the industry. Providers and patients should begin to increase their spending levels, and emerging markets will unquestionably offer expanded opportunities for growth. The new operating realities — US health care reform (particularly the excise tax and comparative effectiveness research), European austerity measures and an expected tightening of the regulatory clearance process in the US — increase uncertainty and risk in the medium term. In the long term, however, the well-documented trends of aging and underserved patient populations, longer life expectancies, expanded elective/lifestyle medicine and new technologies will all fuel industry expansion. ▶

Financing

Reality sets in

US and European medtech companies raised a combined US$13.1 billion in 2009, a 45% jump over 2008, compared to a 38% *decline* between 2007 and 2008. The increase was entirely driven by activity in the US, where financing skyrocketed 88%, largely because of debt financings. In Europe, on the other hand, medtech funding declined about 44%.

The amount raised varied significantly across funding types. Venture capital declined for the second year in a row, falling by 22% in 2009 after having declined by 7% in 2008. IPOs were essentially non-existent for the second consecutive year. However, the overall numbers were propped up by a few large US debt transactions – debt by US medtechs alone accounted for 55% of *all* funding.

The scenario appeared to improve somewhat in the first half of 2010. There was a 20% year-over-year increase in venture capital investment and a rebound in the number of companies willing to test the IPO market – albeit mostly in the US. US debt financing continued to show strength, resulting in a 104% increase in total financing in the first six months of 2010 over the same period in 2009. Of the US$10.5 billion raised thus far in 2010, 68% (US$7.1 billion) has been the result of debt offerings. However, while the debt and follow-on markets have opened for selected companies in the US, Europe's capital markets continue to be sluggish.

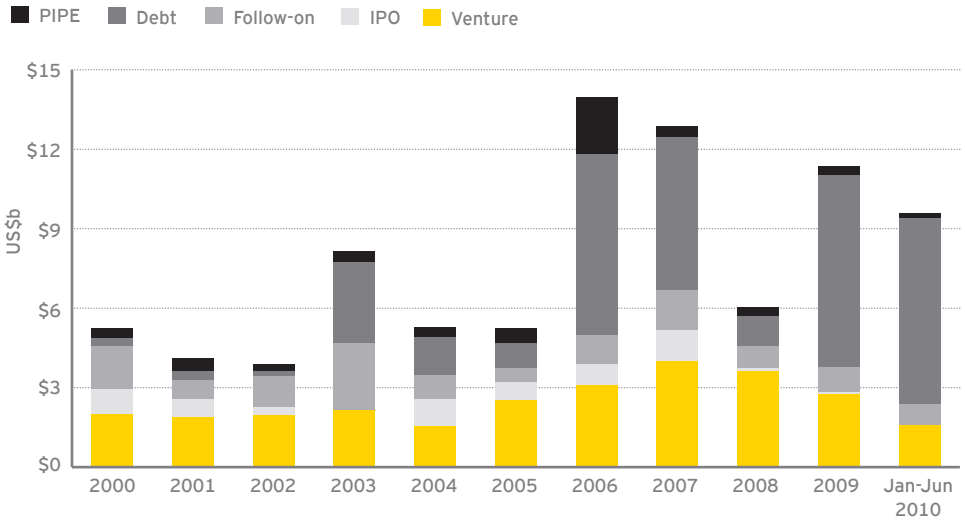
The year in financing – 2009 (US$m)

Type	Combined	Growth	US ($m)	US growth	Europe ($m)	Europe growth
Venture financing	$3,436	-21.5%	$2,735	-24.7%	$701	-6.0%
IPO	$96	-25.1%	$94	-17.7%	$2	-90.5%
Follow-on public offering	$1,729	9.1%	$977	15.3%	$752	2.0%
Debt	$7,243	273.0%	$7,227	550.6%	$17	-98.0%
PIPE	$576	-42.5%	$371	3.1%	$205	-68.0%
TOTAL	$13,081	44.7%	$11,404	88.1%	$1,677	-43.6%

Source: Ernst & Young, Growth is relative to 2008.

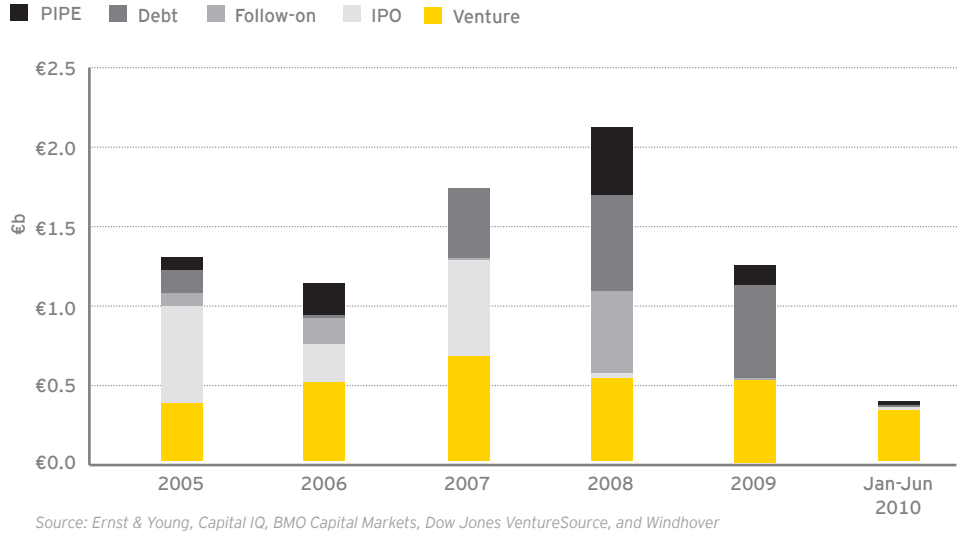
The financing picture that has emerged in 2009 and early 2010 is one where the reality facing different segments is quite divergent. Most large, established medtechs — particularly in the US — have plenty of access to capital. The situation facing smaller, public medtechs and emerging, privately held entities, on the other hand, is worrisome. Despite some improvement in the first half of 2010 on the venture and IPO fronts, many early-stage companies find it challenging to access the capital needed to develop and launch a product. Growing regulatory and pricing pressures, combined with strategic buyers who prefer later-stage assets, are lengthening product development time frames and placing strain on the traditional venture funding model. (For more on the implications for medtech innovation, refer to the introductory article, "The value of innovation.") So even though VC money continues to flow, the majority of it is being reserved for later-stage companies. Unfortunately, this new reality could eventually create a future gap in innovation as otherwise promising new technologies are not able to access the capital to develop past proof of concept.

US yearly medtech financings, 2000–H1 2010



Source: Ernst & Young, Capital IQ, BMO Capital Markets, Dow Jones VentureSource, and Windhover

European yearly medtech financings, 2005–H1 2010



Source: Ernst & Young, Capital IQ, BMO Capital Markets, Dow Jones VentureSource, and Windhover

US financing — the return of the debt market

US medtech companies attracted more than US$11.4 billion of financing in 2009, an 88% increase over the US$6.1 billion that was invested in 2008. At first glance, this extraordinary jump in financing might indicate that the industry has rebounded from the strains of the global financial crisis. However, in reality, a surge in debt offerings by a handful of companies masked the ongoing financing concerns of the majority of industry participants. In fact, of the US$11.4 billion invested in 2009, 83% (US$9.5 billion) was driven by the top 20% of all investment rounds — compared to the 62% that was driven by the top 20% in 2004.

Debt financing accounted for US$7.2 billion, or 63% of the total — which exceeded the record levels of debt capital raised in 2006 and 2007. While venture capital brought in 60% of total financing in 2008, that figure dropped to 24% in 2009, which was more in line with historic levels. The industry also witnessed its first IPO in nearly six quarters (AGA Medical, which went public in Q3 2009), but that was the year's lone initial public offering. This skewed distribution continued in the first half of 2010 as debt accounted for 74% of all US financing, while VC investments represented only 16%. This meant that only 10% of overall financing came from the public markets, versus the 13% in 2009 and an average of 34% between 2000 and 2008. From January to June 2010, the US medtech industry raised US$9.6 billion in financing, including one additional IPO for US$26 million.

From a geographic perspective, California, Massachusetts and Minnesota once again dominated, as companies from these three states attracted 73% (US$15.4 billion) of capital raised in 2009 and the first half of 2010. Minnesota (US$6.3 billion) outpaced Massachusetts (US$4.1 billion) and Southern California (US$3.4 billion) in terms of total fundraising, due to multiple debt offerings by Medtronic and St. Jude Medical that accounted for an astounding 94% of Minnesota's financing. With regard to venture capital, Northern California is the leader by far in both amount raised (US$1.3 billion) and number of deals (48). Massachusetts, Southern California, Washington and Minnesota rounded out the top five in venture capital raised.

European financing — the retreat of the debt market

While debt offerings fueled the significant increase in capital raised by US medtechs, the retreat of debt financing on the other side of the Atlantic resulted in a considerable drop in total capital raised by European medtechs. A total of €1.2 billion (US$1.7 billion) was invested in European medtechs in 2009, a decline of 44%, or more than €800 million (US$1.1 billion), from 2008. The majority of this difference was the result of debt investments, which tumbled 98% from 2008 levels. However, the 2008 debt numbers had been boosted by two companies — Getinge and Fresenius Medical — which raised €565 million (US$831 million) between them. After removing these transactions from the 2008 numbers, overall financing would have declined 17% in 2009. While mature US companies were able to take advantage of historically low interest rates to raise capital, European companies were not as fortunate, as the debt markets were far less receptive to medtech offerings.

During the first half of 2010, European financing was actually up 52% to €659 million (US$873 million) compared to the same period the year before. While a 24% increase in venture investment helped push this total up, Smiths Medical's debt offering was responsible for €300 million (US$397 million). Excluding the Smiths transaction, year-over-year investment would actually be down €75 million (US$100 million), or 17%.

Over the past 18 months, Israel once again led all European nations in both total financing (€278 million; US$369 million) and venture financing (€261 million; US$346 million). Following Israel in total financing were the UK, Switzerland, Germany and France; companies from these five countries were responsible for 56% of all medtech financing in 2009 and the first half of 2010. Israel alone also accounted for 32% of venture funding, while the top five countries mentioned above attracted 77% of Europe's venture capital.

Venture financing

US venture financing

Despite the prevalent pessimism surrounding the "broken venture capital model" (explored in the following section), the US medtech venture market actually turned in a respectable year in 2009. While the US$2.7 billion invested was down from the heights of 2006–08, 2009's total easily surpassed the amounts invested annually

US financings by quarter (US$m)

	Q1 2009	Q2 2009	Q3 2009	Q4 2009	Q1 2010	Q2 2010	Total
IPO	$0	$0	$94	$0	$0	$26	$120
	(0)	(0)	(1)	(0)	(0)	(1)	(2)
Follow-on	$51	$274	$427	$225	$363	$410	$1,749
	(2)	(2)	(4)	(6)	(4)	(9)	(27)
Debt	$1,308	$1,455	$1,456	$3,008	$6,974	$81	$14,282
	(4)	(6)	(23)	(5)	(14)	(23)	(75)
PIPE	$38	$89	$218	$27	$61	$118	$550
	(4)	(10)	(16)	(12)	(11)	(18)	(71)
Venture	$356	$965	$906	$508	$619	$952	$4,307
	(23)	(76)	(112)	(68)	(67)	(111)	(457)
Total	**$1,753**	**$2,782**	**$3,102**	**$3,768**	**$8,017**	**$1,588**	**$21,008**
	(33)	**(94)**	**(156)**	**(91)**	**(96)**	**(162)**	**(632)**

Source: Ernst & Young, Capital IQ, Dow Jones VentureSource, and Windhover
Figures in parentheses indicate number of financings.
Numbers may appear inconsistent because of rounding.

European financings by quarter (€m)

	Q1 2009	Q2 2009	Q3 2009	Q4 2009	Q1 2010	Q2 2010	Total
IPO	€0	€1	€0	€0	€0	€12	€14
	(0)	(1)	(0)	(0)	(0)	(1)	(2)
Follow-on	€11	€67	€463	€0	€7	€0	€548
	(4)	(3)	(3)	(0)	(4)	(0)	(14)
Debt	€4	€9	€2	€0	€ 1	€302	€318
	(2)	(2)	(1)	(0)	(1)	(2)	(8)
PIPE	€75	€12	€5	€56	€20	€ 2	€170
	(8)	(6)	(2)	(6)	(3)	(1)	(26)
Venture	€88	€166	€165	€85	€121	€194	€819
	(35)	(36)	(35)	(20)	(30)	(17)	(173)
Total	**€178**	**€256**	**€635**	**€141**	**€149**	**€510**	**€1,869**
	(49)	**(48)**	**(41)**	**(26)**	**(38)**	**(21)**	**(223)**

Source: Ernst & Young, Capital IQ, Dow Jones VentureSource, and Windhover
Figures in parentheses indicate number of financings.
Numbers may appear inconsistent because of rounding.

between 2000 and 2005. And according to data from Dow Jones VentureSource, US medtech companies received 13.1% of all US venture funding, which represented the highest percentage since at least 2000.

The year certainly started off ominously enough as the US$356 million invested in Q1 was the lowest quarterly venture funding total seen since at least 2000. However, despite the chilling effects of the financial crisis, VCs managed to raise more than US$900 million in both Q2 and Q3.

The pace picked up in 2010, with nearly US$1.6 billion raised in the first half of the year. Should this rate continue, 2010 would easily surpass 2009 on the venture funding front. Interestingly, while the average investment per deal in the first half of 2010 (US$8.8 million) is the second-lowest average for any year in the past decade, the number of deals is on pace to be the highest in the past decade. In fact, 56% of all VC rounds have been for US$5 million or less – whereas in 2007, for instance, this figure was only 34%. So as more and more capital is going toward later-round investments, the amount of funding per round is smaller. The percentage of funding going into late-stage deals in 2009 and the first half of 2010 has reached decade-long highs, with VCs targeting existing portfolio companies or new investments in companies that are close to commercialization or a possible exit. This focus on late-stage funding obviously comes at the expense of emerging medtech companies, which historically have driven the industry's innovation.

Similar to previous years, cardiovascular/vascular, non-imaging diagnostics and orthopedic companies attracted the most

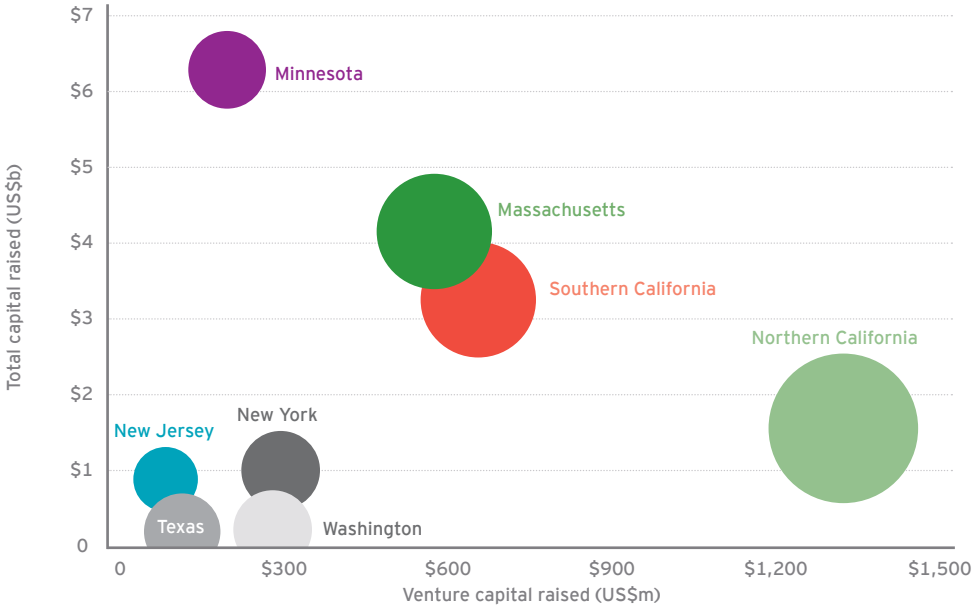
venture investment in 2009 and the first half of 2010. However, in 2009, for the first time since at least 2000, orthopedic led all segments, with US$429 million raised.

European venture financing

European medtechs attracted €505 million (US$701 million) in venture financing in 2009, which was essentially flat compared to 2008 (when €507 million was raised). Similar to the trend in the US, Europe's 2008 and 2009 VC totals were lower than the levels seen in 2006 and 2007, but far exceeded the outlays seen in years prior to 2006. However, the €315 million (US$438 million) invested in the first half of 2010 represents a 24% increase over the first six months of 2009 and puts Europe on pace to reach the levels attained in 2006 and 2007. The increase in venture investment in 2010 was spurred by several large rounds that drove a 67% increase in average deal size – in marked contrast to the US, where average deal size fell during the same period. Venture funding was so strong that it accounted for 48% of total European financing in the first half of 2010 (the comparable figure for 2004 through 2009 was 36%.)

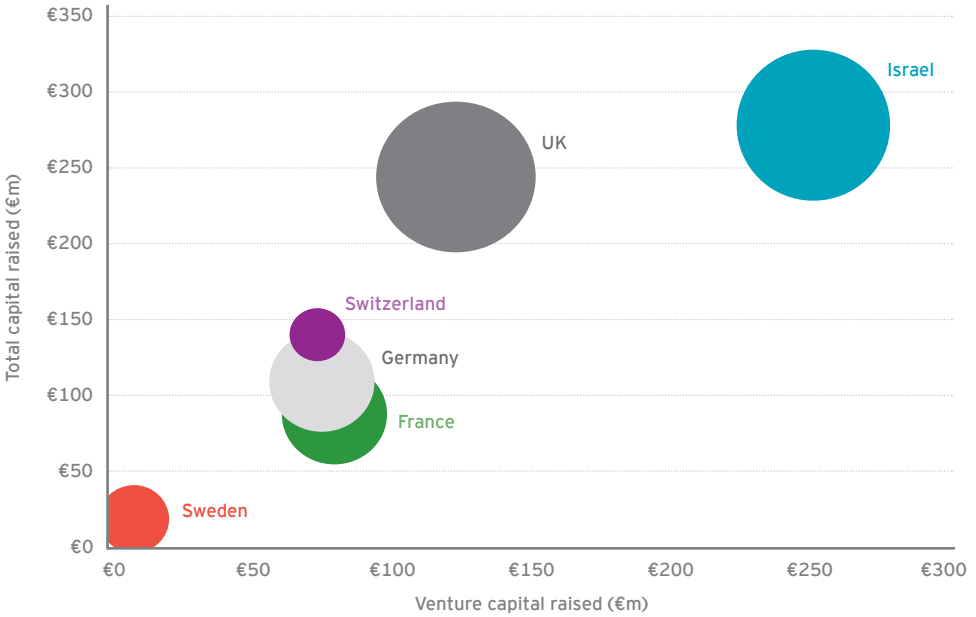
Cardiovascular/vascular and non-imaging diagnostic companies dominated the top 10 venture financings in Europe in 2009 and the first half of 2010. Netherlands Antilles-based Impulse Dynamics, a developer of electrical therapies for the treatment of chronic heart failure, attracted €29 million (US$40 million) in the second quarter to secure 2009's largest venture round. Israel's BioControl Medical, a maker of advanced implantable devices for the treatment of

Capital raised in 2009 and H1 2010 by leading US regions



Source: Ernst & Young, VentureSource, Capital IQ
Size of bubbles shows relative number of financings per region.

Capital raised in 2009 and H1 2010 by leading European countries



Source: Ernst & Young, VentureSource, Capital IQ
Size of bubbles shows relative number of financings per country.

autonomic disorders, received the largest single round in the first half of 2010 with a US$70 million (€53 million) investment by Medtronic. This investment included an option by Medtronic to purchase BioControl for US$550 million (€415 million), subject to the company obtaining US FDA approval for its proprietary implantable nerve stimulation device. In an unusual twist, Medtronic could still acquire the company for US$350 million (€264 million) even if the device fails to gain FDA approval.

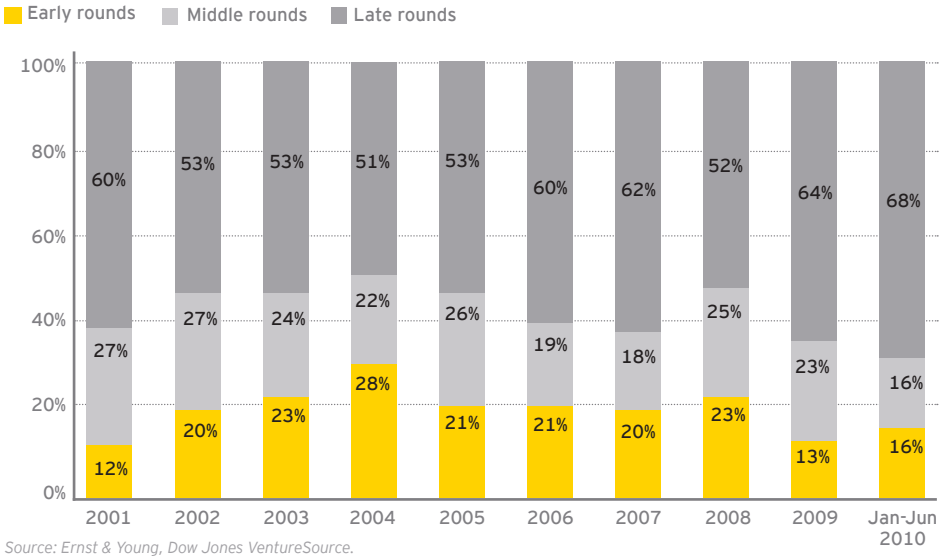
Strains on the VC model

Despite relatively strong aggregate amounts of venture capital raised in 2009 and the first half of 2010, medtech's venture funding model is under pressure. This is the result of factors impacting the venture capital industry overall, as well as sector-specific challenges. The characteristics that have historically attracted VC investors to medtech – shorter, less expensive innovation cycles, straightforward regulatory and reimbursement pathways, and a cadre of potential strategic acquirers – are all under pressure from factors discussed elsewhere in this report: the prospects of a more stringent (and therefore lengthy and more expensive) regulatory clearance process; a more challenging reimbursement environment, including the specter of comparative effectiveness studies; and strategic acquirers who are primarily interested in targets with commercialized products.

In the absence of a strong recovery in exit valuations (unlikely in the near term), all of these factors will put pressure on investment returns. When coupled with the fact that inflows to venture funds overall have decreased significantly as limited partners adjust to diminished portfolios and rethink their capital allocations, the likely result is that the number of active venture investors in the sector contracts. Fewer investors and less money overall will both raise the bar in terms of the technologies that are funded and dampen valuations. VCs will be forced to triage their portfolios and make difficult decisions on which entities to continue to support. For new ventures, they are likely to invest increasingly with executives or serial entrepreneurs who have had previous success, and in companies that have a clear, well-thought-out regulatory and reimbursement pathway. While increased selectivity and discipline may result in an overall improvement in the quality of early-stage companies, the risk is that investors become too selective and unwilling to fund potentially breakthrough technologies, which in the long term negatively impacts patients and the industry's growth prospects.

Without question, this makes for a very difficult environment for existing venture-backed companies that need additional capital to complete development and pursue a launch but have limited options to raise capital in the public markets or from other sources. Therefore, we expect to see companies whose products are not sufficiently differentiated from either a technology or efficiency perspective to have an increasingly difficult time accessing capital.

US venture investment by rounds
VCs are increasingly gravitating towards later-stage investments



Source: Ernst & Young, Dow Jones VentureSource.

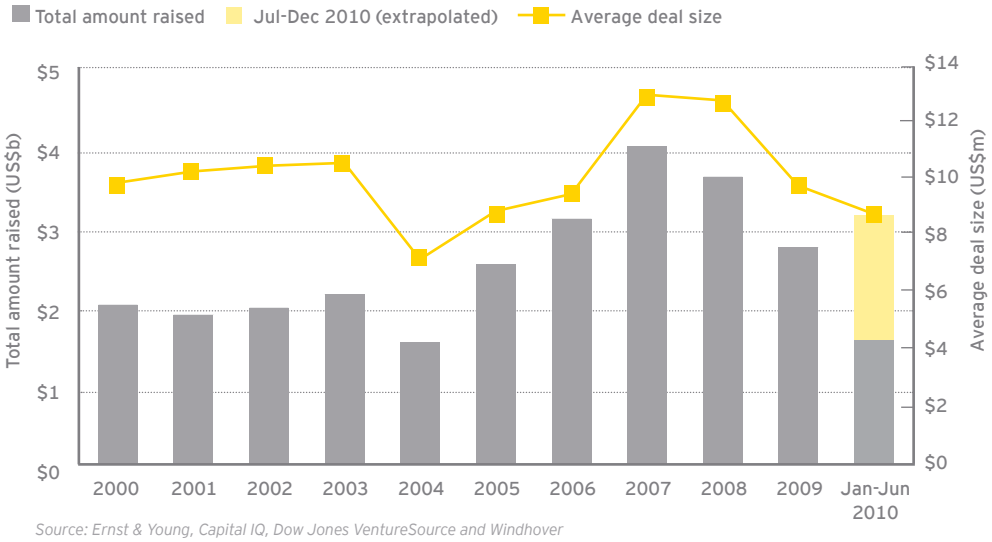
IPOs

US IPOs

The US medtech industry averaged more than 14 IPOs per year between 2004 and 2007. After three IPOs hit the market in the first quarter of 2008, the IPO window abruptly shut for nearly six quarters. As we documented in last year's *Pulse* report, while the disappearance of IPOs in 2003 was attributed to the lack of investor enthusiasm for the industry, the most recent dearth of IPOs was the result of systemic issues affecting the capital markets. Between the end of 2007 and the first half of 2009, at least 16 venture-backed companies were forced to pull their IPO filings in the face of chilly investor sentiment.

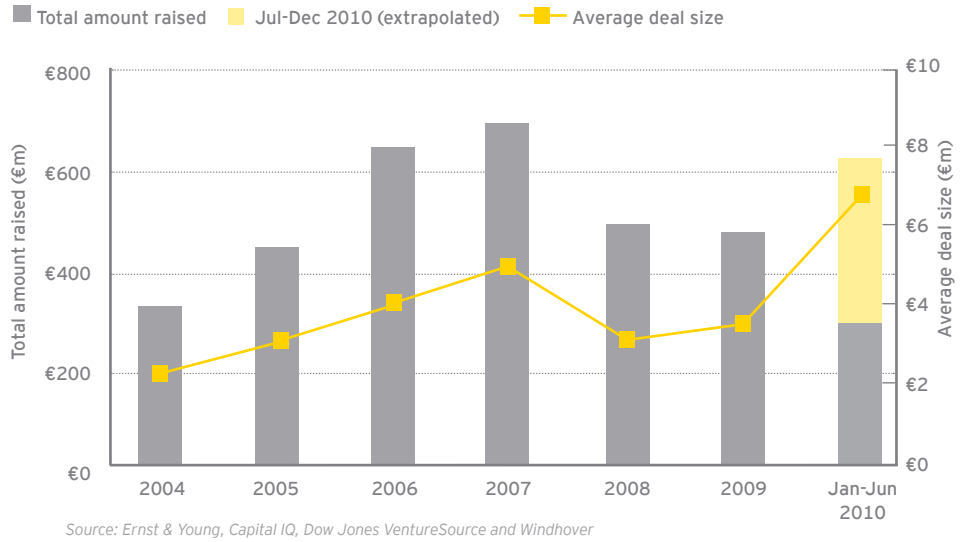
In October 2009, the six-quarter drought of IPOs came to an end when Minneapolis-based AGA Medical, a manufacturer of devices for the treatment of structural heart defects and vascular abnormalities, went public. Founded in 1995, AGA Medical raised US$94.4 million, while the company's co-founder and other stockholders sold additional shares for another US$105 million. AGA Medical, which had initially filed for a US$200 million IPO in June of 2008, priced its IPO below the expected range and planned to use the majority of its proceeds to pay down debt. Unfortunately, it took another seven months before the US market saw another medtech IPO — Pasadena, California-based GenMark Diagnostics' May 2010 offering. GenMark, a provider of automated, multiplex molecular diagnostic testing systems, raised US$26 million. Like AGA, GenMark's IPO priced below its initial filing range.

US venture capital, 2008–H1 2010



Source: Ernst & Young, Capital IQ, Dow Jones VentureSource and Windhover

European venture capital, 2004–H1 2010



Source: Ernst & Young, Capital IQ, Dow Jones VentureSource and Windhover

Top 10 US venture rounds of 2009 and H1 2010

Company	Location	Product type (disease)	Gross raised (US$m)	Quarter	Round
Small Bone Innovations	New York, N.Y.	Therapeutic devices (orthopedic)	$108	Q2 2009	4
Intuity Medical	Sunnyvale, Calif.	Non-imaging diagnostics	$64	Q1 2010	4
TransEnterix	Research Triangle Park, N.C.	Therapeutic devices (non-disease-specific)	$55	Q4 2009	2
PhotoThera	Carlsbad, Calif.	Therapeutic devices (neurology)	$50	Q2 2009	5
Calypso Medical	Seattle, Wash.	Therapeutic devices (oncology)	$50	Q2 2009	5
ConforMIS	Burlington, Mass.	Therapeutic devices (orthopedic)	$50	Q2 2009	2
Home Dialysis Plus	Portland, Ore.	Therapeutic devices (hematology/renal)	$50	Q2 2010	1
TearScience	Morrisville, N.C.	Therapeutic devices (ophthalmic)	$45	Q2 2010	2
Pathway Medical Technologies	Kirkland, Wash.	Therapeutic devices (cardiovascular/vascular)	$43	Q2 2009	8
Oraya Therapeutics	Newark, Calif.	Therapeutic devices (ophthalmic)	$42	Q2 2009	3

Source: Ernst & Young, Capital IQ, Dow Jones VentureSource and Windhover

Top 10 European venture rounds of 2009 and H1 2010

Company	Location	Product type (disease)	Gross raised (€m)	Quarter	Round
BioControl Medical	Israel	Therapeutic devices (cardiovascular/vascular)	€58	Q2 2010	8
Impulse Dynamics	The Netherlands	Therapeutic devices (cardiovascular/vascular)	€29	Q2 2009	2
Endosense	Switzerland	Therapeutic devices (cardiovascular/vascular)	€26	Q3 2009	2
Oxford Immunotec	United Kingdom	Non-imaging diagnostics	€22	Q3 2009	5
Curetis	Germany	Non-imaging diagnostics	€20	Q4 2009	2
Spectrum Dynamics	Israel	Imaging	€20	Q2 2009	1
JenaValve Technology	Germany	Therapeutic devices (cardiovascular/vascular)	€19	Q1 2010	3
Cheetah Medical	Israel	Non-imaging diagnostics	€16	Q1 2010	2
Symetis	Switzerland	Therapeutic devices (cardiovascular/vascular)	€15	Q2 2009	4
Agendia	The Netherlands	Non-imaging diagnostics	€15	Q3 2009	5

Source: Ernst & Young, Capital IQ, Dow Jones VentureSource and Windhover

In 2010, the overall IPO market has seen a significant increase in activity as the capital markets have begun to open up. Against this backdrop, at least nine US-based medtechs filed to go public in the first nine months of the year while another postponed its expected IPO due to unfavorable market conditions. While further market uncertainty and poor aftermarket performance may derail a full-scale IPO resurgence, it appears that the US medtech IPO market may show some signs of life in the months ahead.

European IPOs

The European medtech industry had a second consecutive subpar year on the IPO front in 2009. After attaining an average of at least €220 million worth of IPO volume per year between 2004 and 2007, the European industry only had one IPO in 2009 – Sweden's Dignitana AB, which raised a very modest €1.3 million (US$1.9 million) in the second quarter. This represents the lowest annual amount raised via IPO since at least 2004 and comes on the heels of a disappointing 2008 when there were only two listings, for a combined €13.4 million (US$19.7 million). The trend continued in the first half of 2010, when

Initial public offerings
IPOs completed in 2009 and H1 2010

Company	Location	Product type (disease)	Amount (US$m)	Date
AGA Medical	Minneapolis, Minn.	Therapeutic devices (cardiovascular/vascular)	$94	October 2009
GenMark Diagnostics	Pasadena, Calif.	Non-imaging diagnostics	$26	May 2010

Selected companies in the IPO pipeline as of 30 June 2010

Company	Location	Product type (disease)	Filing size (US$m)	Filing date
Autogenomics	Carlsbad, Calif.	Non-imaging diagnostics	$86	July 2008
Rules-Based Medicine	Austin, Texas	Non-imaging diagnostics	$90	December 2009
SurgiVision	Irvine, Calif.	Imaging	$35	December 2009
BG Medicine	Waltham, Mass.	Non-imaging diagnostics	$86	January 2010
Kips Bay Medical	Minneapolis, Minn.	Therapeutic devices (cardiovascular/vascular)	$58	April 2010
Atossa Genetics	Seattle, Wash.	Non-imaging diagnostics	$15	May 2010
Electromed	New Prague, Minn.	Therapeutic devices (respiratory)	$14	May 2010
Tornier B.V.	Schiedam, Netherlands	Therapeutic devices (orthopedic)	$205	June 2010
BioHorizons	Birmingham, Ala.	Therapeutic devices (dental)	$100	June 2010

Source: Ernst & Young, DeviceSpace and BMO Capital Markets

only one company — Aposense, a molecular imaging company — launched an IPO. The Israeli-based company raised US$16 million (€11.5 million) in the second quarter, which was coupled with an additional US$8 million (€5.8 million) private placement. While the pipeline for US medtech IPOs continues to grow, European company filings seem to be well behind, which would indicate that a sustainable IPO market is still not in sight.

US perspective — other financing

As mentioned above, debt offerings by public medtechs constituted the lion's share of funds raised in 2009. Of the US$7.2 billion raised via debt financing, 93% went to just six companies: Boston Scientific (US$2 billion), Medtronic (US$1.25 billion), St. Jude Medical (US$1.2 billion), Zimmer (US$1 billion), Becton Dickinson (US$750 million) and Beckman Coulter (US$500 million). This trend continued in the first half of 2010, when companies such as Medtronic (US$3 billion), Life Technologies (US$1.5 billion), Stryker (US$1 billion) and Thermo Fisher (US$750 million) took advantage of a US credit market that is offering historically low interest rates for high-quality issuers. While some companies had an immediate need for capital, several entered into these transactions opportunistically and plan to use the funds to either buy back stock or seek value-creating acquisitions.

While the massive amounts of debt being poured into the US industry may have stolen the financing headlines, both follow-on public offerings and PIPE investments also saw growth in 2009. Follow-on outlays jumped 15% to US$977 million with roughly 61% being derived from offerings by Beckman Coulter and Sirona Dental. Although the US$977 million raised in 2009 was well below the figures seen in 2006 and 2007, the level of activity in 2010 is on pace to surpass both of those years. In the first half of 2010, more than US$770 million in follow-ons had been completed, of which US$256 million was the result of Sirona Dental's offering. On the PIPE front, proceeds edged up 3.1% to US$371 million in 2009, which, after 2008, represents the second-lowest showing since 2002. PIPE activity has remained slow in the first half of 2010.

European perspective — other financing

Unlike their counterparts in the US, European medtechs were largely unable to access debt in 2009 and the first half of 2010. European debt figures dropped 98%, from €565 million (US$830 million) in 2008 to just €12 million (US$17 million) in 2009. However, the 2008 total included very large transactions by two companies — Getinge and Fresenius Medical. Without the impact of these deals, 2008 would have resembled 2009 and many of the years that preceded it.

European medtechs also saw their involvement with PIPEs fall sharply as these investments brought in €148 million (US$205 million), off 68% from 2008. On a positive note, the year did see a modest 2% jump in follow-on investments to €541 million (US$752 million). However, of the €541 million in follow-ons, 85% of it was derived from Qiagen's €429 million (US$630 million) offering. Netherlands-based Qiagen announced that it would use the net proceeds to fund its acquisition of DxS — a UK-based provider of molecular diagnostics — for up to US$130 million including contingency payments, as well as to fund other potential acquisitions. Qiagen went on to acquire SABiosciences of Frederick, Maryland, for US$90 million in late 2009 and Germany's ESE Gmbh for US$19 million in early 2010.

In the first half of 2010, both follow-on and PIPE funding activity is trailing well behind the figures raised during the comparable period in 2009.

Outlook

While the fundraising numbers in 2009 may appear strong, it is telling that the totals were in fact propped up by a few very large debt transactions. The reality that has now set in for medtech financing is in fact two different realities. Established US companies have had no trouble raising large amounts of capital. But for many emerging firms, the situation is very different. Of particular concern is the strain on venture funding and its implications for medtech innovation. With the situation relatively unchanged in 2010, these firms will have to become increasingly creative in searching for funding — or increasingly efficient in deploying the resources they have.

Roundtable on financing and M&As

Dealing with challenges

John Kehl
Edwards Lifesciences LLC
Corporate Vice President, Strategy & Corporate Development

Josh Makower, MD
ExploraMed Development, LLC
Founder and CEO

Michael Neuberger
BMO Capital Markets Corp.
Managing Director and Sector Head, Healthcare Investment Banking

Financing and acquisitions have always had a symbiotic relationship in the medical technology industry. Venture funding has seeded the start-ups that typically develop next-generation technologies, and those companies have, in turn, often been acquired by large medtech companies for their pipelines. After reaching lofty heights in 2006 and 2007, venture funding and M&A activity plummeted in the wake of the global financial crisis. While we have recently seen a rebound in financing and transaction activities, a host of other challenges — health care reform and regulatory and reimbursement changes — continue to place the medtech funding-and-acquisition model under considerable strain.

To get some insight into this changing business environment, we sat down with three industry veterans who have extensive and varied experience in the financing and acquisition of medtech companies. **John Kehl** has led Edwards Lifesciences' strategy and corporate development functions for the past 10 years. **Josh Makower**, Founder and CEO of medical device incubator ExploraMed Development, and Venture Partner with New Enterprise Associates, sold Acclarent to Johnson & Johnson for US$785 million in January 2010. **Michael Neuberger** offers more than 25 years of health care investment banking insights from his role at BMO Capital Markets.

Their responses highlight the considerable challenges in today's financing and M&A environment — from scarcity of capital to risk-averse buyers and looming changes on the regulatory and reimbursement fronts.

To succeed, medtech companies will need not only to innovate new technologies, but also to innovate new business models.

Ernst & Young: Recently, we have seen medtech acquirers migrating from development-stage (preapproval) companies toward targets with commercialized technologies and established revenue. Do you see this trend continuing? If so, what are the long-term implications of this development?

Makower: With regard to long-term implications, I think we've already seen a severe impact on venture investment strategies. Venture-backed companies are not only taking longer to obtain marketing clearance for their products, but as was stated in the question, investors are now required to fund these companies well into the commercialization stages, and that takes substantially more capital. If venture syndicates are not prepared to invest more money to fund later-stage development and expansion, then companies will run into big trouble. Innovation will ultimately be affected by this as fewer dollars are available for earlier-stage companies. Also, venture investors will be cautious about backing technologies that don't have the capacity to operate as freestanding businesses. Further, if a technology cannot ultimately be successfully distributed by a larger acquirer, it may be extremely challenging for investors to get a reasonable return on their investment as the IPO options remain unfavorable.

"While acquirers are clearly hedging their risks by seeking companies with commercialized operations, I am also seeing the definition of 'commercialization' broadening. If a company can demonstrate 'proof of commercialization' with good clinical data supported by some sort of limited market acceptance, then that may be sufficient enough for some buyers."

Kehl: While acquirers are clearly hedging their risks by seeking companies with commercialized operations, I am also seeing the definition of "commercialization" broadening. If a company can demonstrate "proof of commercialization" with good clinical data supported by some sort of limited market acceptance, then that may be sufficient enough for some buyers. Regardless, from Edwards' point of view, targets need to be beyond regulatory approval because regulatory approval by itself isn't always a great indicator of commercial success.

I am also seeing a middle ground emerge where strategic acquirers are relying more on structured acquisitions — based on milestones or other modifications — to mitigate the risk left in earlier-stage transactions. For example, a potential target's clinical data may be underdeveloped, or it may have a European CE mark but be lacking clinical approval in the US.

Neuberger: We have seen this trend before, but to be honest, I don't think anything has fundamentally changed on the part of acquirers. Yes, buyers are being a bit more conservative, but they are doing things that are extremely logical. They're looking at their product portfolios and their competitive positions, and they're trying to determine how an acquisition may increase revenue growth, drive down costs or add innovative technologies. What's different about that?

With early-stage sellers, it's a slightly different issue. Early-stage sellers are certainly more anxious as they are in a much more weakened position due to the general lack of activity by acquirers. Many smaller, innovative companies that have relied on VC investments are constrained by a lack of available capital. The venture funding model — as it currently exists — is in trouble. Where VCs might have been able to bet on a half-dozen companies at a time, they now may only be willing to bet on two or three — and as Josh points out, that is going to hurt innovation in the long run.

Ernst & Young: As you evaluate transaction or investment opportunities, what assumptions are you making about the price and volume that products will be able to achieve in the current market environment?

Kehl: In the current economic environment, a combination of factors such as the increased push for cost-effectiveness, pressures on health care budgets, and even an increased need for new pricing and modeling technology, have resulted in more conservative pricing assumptions. Reimbursement is now a primary consideration in pricing assumptions, and most companies are less positive about average sales price (ASP) going forward. Unit volumes, to me, are very different and are treated more on a case-by-case basis, based on demographics, individual geographies and the clinical utility of each product.

Neuberger: As John said, everybody is clearly looking at their price and volume models more conservatively than they may have in the past. Medtech's best and brightest don't fully understand the impact that reform, the FDA and the weak economy will have on their business long term, so they're naturally going to hold back, which will reduce the volume of M&As. The deals that are getting done are mostly in the margin — you're not seeing very many larger deals. If you're a me-too product company, then you should definitely expect to lower your revenue, cost and volume assumptions, which will impact takeout values. However, if you're a company with minimally invasive, low-cost, high-efficacy solutions, you're more likely to see acquirers

willing to take a risk on the technology and pay a higher premium.

Ernst & Young: Early-stage venture funding has dropped roughly 20% since 2007. What implications will this have for medtech innovation?

Kehl: This decline in early-stage funding will undoubtedly impact the pace of innovation – there's no way around it. We've seen down cycles before, but this one is a bit tougher. It's not that investors are less interested in medtech – it's just that there's less investment capital available. With acquirers in the driver's seat, VCs have to nurture their early-stage investments for longer. This ties up their capital longer than they had probably planned and leaves less money to fuel the next wave of start-ups. As a result, I am seeing more companies gravitate toward a "Europe first" strategy that focuses start-up activities and proof-of- concept development outside the US. The intention is that early-stage companies can avoid the costs and regulatory hurdles that are encountered in the US, yet gain enough traction and market acceptance to attract the interest of a strategic acquirer that would then take on the US clinical trial and approvals process.

Makower: The implications for innovation and patient care are significant. This decrease in investment is primarily driven by the increased time and money it is taking companies to effectively navigate the US regulatory and reimbursement systems. This issue is negatively affecting innovation in the US and the long-term effects will be nothing short of devastating. If we as entrepreneurs can't make a compelling case to the venture community that medtech is a profitable place to invest, access for patients to new medical technologies will decrease and patient health will ultimately suffer. This is a big issue, so we immediately need to address these hurdles in Washington – there is a lot at stake for patients.

Neuberger: To me, this is where there should be a flashing red light on the industry. Since valuations have not dramatically improved in medtech for some time, VCs will continue to err on the side of investing later and will accept smaller ultimate exits. Unfortunately, we're seeing institutional and corporate investors pulling back as well, so I think we've got a real threat to the pace of innovation in the short term. However, I think history would say that such voids and cycles can create a huge potential opportunity for a new cadre of investors who will fund and accept innovation risk that is not now being adequately funded by present VCs. I don't know who these investors are, but I suspect they'll deploy smaller funds. Instead of raising and investing US$500 million funds, we will see people splinter off from where they are and establish smaller, perhaps US$50 million funds. These smaller funds will be able to invest in early-stage companies and technologies and hopefully become feeder mechanisms for innovation as we move forward.

Ernst & Young: Over the past year, we have seen a number of product companies diversify by either acquiring services capabilities or forming joint ventures with non-traditional players. Do you see this trend continuing? If so, what areas are medtech companies likely to target?

Kehl: I am seeing the beginnings of this trend in diagnostics and wireless patient monitoring. But the success of these transactions is going to depend on how much value they create. As companies experience increased reimbursement and regulatory pressure, we are seeing more focus on reinventing business models. The question then becomes, "How do you deliver value to the system and improve patient outcomes?" I don't think you'll see strategic investments, formal acquisitions or joint ventures, but rather, short-term partnerships as companies test different business models.

Neuberger: I agree with John and also see many of the same trends, especially in the area of diagnostics. We are also seeing this trend in other areas, such as the monitoring of medication usage, the performance of certain implantables and their impact on a patient's condition, as well as "smart" durable medical equipment, such as wireless monitoring of patient vital signs in the home, hospital and post-acute settings. These technology-enabled solutions seek to build an efficacious and low-cost bridge between the patient, payor and provider. I suspect we will continue to see much more of this going forward.

Makower: While there may be some unique opportunities to take a non-traditional

approach, I don't see this being a global or universal strategy. I haven't seen any evidence to suggest that the traditional ways of doing business don't still make the most sense. There may be certain circumstances where incorporating a service element into a product-based business or using a joint venture may make sense, but it would be purely on a product-by-product, company-by-company basis and unlikely to be a major trend away from traditional business practices.

Ernst & Young: What opportunities do emerging markets present for medtech companies?

Neuberger: From the perspective of investors, the world has become extremely flat. If a company is not playing in emerging markets, it is missing key opportunities

> "If an exemption is not implemented, venture capitalists will be forced to divert investment funds to pay the tax so that their portfolio companies can stay afloat. This would then become a tax on investment – and by implication, a tax on innovation – which is a problem in this innovation-driven industry."

and runs the risk of becoming obsolete. Over the last several years, the most successful approach has been to develop a relationship with a domestic partner that is knowledgeable and has an established presence in the market. It is very rare that companies have successfully established their own emerging market strategies without such in-market alliances.

Kehl: Edwards was fortunate to inherit a relatively expansive global footprint – larger than a company our size would normally have – when we were spun off from Baxter in 2000. We are somewhat unique because our immediate growth priorities are in developed markets where we expect a good return on some pretty unique innovations that are in the final stages of development. However, over time, emerging markets will become more important to us. In fact, one of our long-term goals is to build a successful business in China. As we grow, I doubt M&As will play a big role in our expansion into markets such as China, but as Mike just shared, I also believe that strategic partnerships will fuel our future growth.

Makower: Despite the promise of emerging markets, I think many are still very high-risk and need to be approached with great caution – even for large companies. Some markets have a bias toward local companies and their intellectual property laws are difficult to enforce, so that can put foreign entities at a significant disadvantage. To successfully compete in these emerging markets, foreign companies may need to deploy some novel strategies that differ substantially from the way they approach more traditional markets overseas. So yes, while I think it makes sense for big companies to produce a similar collection of technologies within the emerging markets, there are many risks to consider.

Ernst & Young: Now that healthcare has been passed in the US, what potential impact do you see on the medtech M&A and financing environment?

Makower: As far as I can tell, the majority of health care reform is going to have a neutral impact, on average, for the medtech industry. However, there are two features of health care reform that are very troubling, and they could have a disastrous effect if they aren't fixed since investors dislike uncertainty. Number one, the medical device tax needs to have an exemption for small companies that have revenue but are not yet profitable. This would include exempting the first US$100 million–US$150 million in US sales from the tax. The investment required to establish a new technology is significant, and medtech companies can operate for years without making a profit. While it may be reasonable to tax the net income of profitable companies, it's not reasonable to tax unprofitable companies on their revenue. If an exemption is not implemented, venture capitalists will be forced to divert investment funds to pay the tax so that their portfolio companies can stay afloat. This would then become a tax on investment – and by implication, a tax on innovation – which is a problem in this innovation-driven industry.

The second area of uncertainty involves comparative effectiveness research. If executed well, comparative effectiveness research may be a great tool to guide physicians and patients toward the most effective therapies. If used incorrectly, however, it could screen out new technologies

that have not yet gained a foothold, thus killing innovation and the chance to establish new standards for improved patient health and quality of life. So while the details are being worked out, we need to keep a close and careful eye on the discussion and make sure that any new system will not block innovation from reaching the market. (For more information on this subject, please see Wendy Everett's article in this report, "Medtech and comparative effectiveness research.")

Kehl: I think it's too early to know what the full impact of all this will be. Reform initiatives and efforts to curb health care costs are certainly going to increase pressure on the industry to lower prices. This will have to be addressed before any company sees the benefit of more patients in the system. And different companies will face different pressures depending on their product offerings. However, like Josh, I believe the device tax will hurt growth as medtech companies resort to broad cost-cutting measures — from jobs to R&D spend — to offset the higher tax bill. When you put all these forces together, this could drive more industry consolidation as companies, particularly smaller, early-stage companies, look for efficiencies to lower costs and improve margins. We'll have to see how it all plays out.

Neuberger: Thirty million people coming into the system is a positive development for the industry. However, I'm not sure if anyone knows whether these new numbers will mitigate the obstacles Josh and John have mentioned. What I do believe is that there is going to be an impact on companies, large and small, as they try to make up for the tax. While the tax won't fundamentally change the industry, companies will need to adjust their cost structures and their spending, and this could lead to more acquisitions motivated by cost synergies. While I am not generally in favor of increased taxes on medtech companies, I don't believe this tax by itself is the draconian, system-wide death knell others believe it will be. But the tax, in combination with issues such as the current regulatory environment, comparative effectiveness and other financial issues, is definitely enough to keep medtech CEOs up at night.

Ernst & Young: Has the uncertainty around potential changes to the 510(k) clearance process impacted the M&A and financing environment for medtech?

Kehl: The potential changes to the 510(k) clearance process are more signs that the FDA is intent on tightening its product approval process. With changes to the regulatory process come increased risk and costs, which hurt the medtech M&A and financing environment. While bigger companies can probably handle the uncertainty and unpredictability in the current product approval process — and absorb the added costs — it can impose a crushing burden on smaller companies with limited capital and resources. Without a clearly defined path or proven product competency, these start-ups will also have a difficult time raising capital or finding acquirers. So it's the small companies that are experiencing the biggest toll from the FDA's uncertainty.

Makower: The uncertainty associated with the US regulatory processes in general has become worse — as John said, it has become unpredictable and onerous. Balancing benefits and risks in the regulatory approval process appears to have been lost, and we are already seeing companies fleeing to Europe, US jobs being lost, companies closing and talented young minds seeking other areas of pursuit. It's important to point out that it's not just the shadow over the 510(k) process that is a concern — the changes to the 510(k) process are a completely different issue, primarily driven by a sense that there is a safety issue. However, the data does not support these assertions. In addition, the 510(k) process has already been reviewed by the US Government Accountability Office (GAO), and its report did not produce a substantial amount of evidence to support that the process needs to be radically changed. Further, recent data from the University of Minnesota presented to the Institute of Medicine further underlines there is no evidence to suggest the 510(k) process itself has a major safety issue. While no process is perfect and there is always room for improvement, it's frustrating — given the negative impact this has had on the industry — to realize so much of this focus has been driven by anecdote and headlines rather than data. Again, it's important to differentiate the issue of changes to the 510(k) process from the real issue: the need for more transparency, predictability, reliability and reasonableness at the FDA. Until these conditions are addressed, the environment for financing or acquisitions will continue to be difficult.

> " ... I don't believe this tax by itself is the draconian, system-wide death knell others believe it will be. But the tax, in combination with issues such as the current regulatory environment, comparative effectiveness and other financial issues, is definitely enough to keep medtech CEOs up at night."

Neuberger: I agree with Josh. Of all of the things we've talked about, I think the current FDA environment – risk aversion, disregard of pre-cleared approaches, substantial time delays, etc. – is far and away the biggest issue impacting the future of the medical technology industry. The FDA has created an environment that makes it extremely difficult for companies to determine the right course of action for moving their science and technology forward. The system needs to get fixed so that the rules aren't constantly changing in the middle of the game – we need regulatory reform that is clear, well understood and consistent.

Ernst & Young: Where do you see the medical technology industry in five years?

Makower: Overall, the medtech industry will continue to grow, primarily due to the continued increase in the aging population. However, larger firms will have a larger market share as many smaller medtechs struggle to survive independently in an increasingly challenging financing and regulatory climate. If the FDA environment does not improve, we may even see – for the first time ever – a meaningful reduction in the number of small US medtech firms. This would be detrimental to patient care since most meaningful innovations are developed by emerging companies.

Neuberger: The number of small medtech players will be significantly smaller in five years and the industry will be increasingly dominated by larger and larger players. The pace of innovation will slow down due to a sustained lack of capital, and the industry's largest players will be unable to completely fill the innovation gap. These large firms will also face continued pressure on top-line growth as regulatory and reimbursement challenges accelerate. Finally, big pharma will once again become a significant strategic investor as pharma companies take over many of today's largest medtech firms.

Kehl: Regulatory approval timelines will probably get longer and more expensive before they improve, so you probably will see more collaboration between VCs and strategic investors around early-stage technologies. Regardless, fewer ideas are likely to get funded and innovation will suffer. Companies will face increased pressure on government reimbursement because of the economic slowdown and the need to cover more beneficiaries. So demonstrating the cost-effectiveness of new technologies will become increasingly important. In this environment, new technologies with demonstrated clinical utility and cost-effectiveness will be increasingly critical and relatively scarce, so I expect to see buyers assigning high values to these assets. ▶

Mergers and acquisitions

A buyers' market

Medical technology is a transaction-focused industry. Next-generation products and technologies typically developed by entrepreneurial companies form the innovative backbone of the industry. While mature medtechs typically spend upwards of 8%–10% of their revenues on research and development, the majority of these companies use acquisitions to supplement their internal pipeline development. Gaining access to novel devices and technologies is an essential component of the business model for medtech's larger players, which are particularly skilled at manufacturing, commercializing and enhancing acquired technologies through successive product releases.

Over the years, the marriage between medtech targets and their acquirers has often been mutually beneficial. Many private, early-stage companies have been able to sell their technologies late in development, providing the management team and investors a return while allowing a more-seasoned acquirer to assume the risks and costs associated with product approval, launch and commercialization. In addition to acquiring early-stage technologies, mature acquirers (large medtechs, pharmaceutical companies and private equity firms) have also looked to established companies and carve-outs to give top-line growth an immediate boost, diversify portfolios and increase focus on core assets. Medtech deal activity reached its peak in 2006 and 2007, when the industry not only witnessed record numbers of deals and total deal values but also saw historic amounts of venture capital and private equity invested. More recently, the great recession, health care reform, regulatory challenges and a litany of other obstacles have put a damper on deal activity.

A lingering recession

When the financial crisis struck in the third and fourth quarters of 2008, the market for medtech transactions essentially collapsed. With stock prices in free fall, credit markets frozen and growing recessionary fears, most strategic acquirers sat on the sidelines well into 2009, with the exception of a few companies, such as Abbott, Covidien, Inverness Medical Innovations (now Alere) and Medtronic.

As a result, 2009 was the worst year for medtech transactions since 2002. A total of 172 deals were completed in the US and Europe in 2009, with an aggregate announced value of US$15.7 billion — representing declines of 28% and 62%, respectively, from comparable figures in 2008. While the first half of 2010 has seen a pleasant rebound — to 90 deals with a total value of US$45.2 billion, or US$16.9 billion excluding Novartis' US$28.3 billion takeover of Alcon — a number of market issues will continue to have a ripple effect on transactions through the remainder of 2010 and beyond.

With the worst of the financial crisis apparently over, and some increased clarity on US health care reform and the market and regulatory environment, we are starting to see strategic acquirers appear more willing to pull the trigger on transactions. While some buyers continue to preserve cash and balance sheet flexibility in the face of lukewarm stock valuations, a number of signs indicate that the M&A market may be starting to recover.

First, during the past year, small medtechs and their investors have begun to accept the reality of their lower valuations, enabling a slight uptick in "bargain hunting" by strategic acquirers (e.g., Medtronic/ATS Medical and Covidien/Somanetics). Second, US credit markets have become very receptive to medtech debt, and companies such as Abbott, Medtronic and Stryker have taken advantage of low interest rates to complete a series of strategic acquisitions. Third, some forward-looking acquirers have been targeting next-generation technologies (e.g., Medtronic/CoreValve and Ablation Frontiers; Abbott/Evalve) or opportunities to diversify product portfolios (e.g., Novartis/Alcon, Abbott/Advanced Medical Optics, Covidien/ev3).

Seeking maturity

The decline of M&A activity over the past couple of years has resulted in anxiety for many venture investors and their portfolio companies. Additionally, the anemic IPO market has made investors' exit strategies — once fairly predictable — a lot more challenging. This new reality has forced scores of VC-backed companies to operate independently for longer than originally anticipated by their investors. As a result, acquirers have much more bargaining power when setting M&A terms with early-stage medtechs. Medtech acquirers have less appetite for risk, and their interests have continued to migrate from developmental, pre-approval companies toward firms that have commercialized their technologies and, in many cases, demonstrated revenue growth. Since regulatory approval alone is no longer a reliable indicator of success, acquirers have been requiring targets to demonstrate solid clinical data and a degree of market acceptance. Despite very favorable valuations, acquirers are not buying assets just because they are cheap. They are focused on creating value for the long term and understand that a bad deal done cheaply is still a bad deal.

This new reality has also driven changes in medtech's venture funding model, which has traditionally been built on quick, predictable exits. In a market with fewer potential acquirers, deflated valuations and less leverage in negotiations, early-stage companies expect to have to finance themselves for a longer period of time and to expend resources adding capabilities such as sales, distribution and reimbursement expertise. While establishing commercial operations is often inefficient in the long run — especially at a macro level, since most acquirers will likely regard these functions as redundant to their own operations — it will become increasingly unavoidable for reaching an exit. As Joshua Makower of ExploraMed Development states in the "Dealing with challenges" roundtable, "if venture syndicates are not prepared to invest more money to fund later-stage development and expansion, then companies will run into big trouble."

The year in transactions — 2009 (US$m)

Type	Combined	Growth	US	US growth	Europe	Europe growth
Total deals	172	-28.0%	128	-13.5%	65	-52.6%
Total deals with terms announced	90	-20.4%	69	-12.7%	31	-46.6%
Total deal values	$15,700	-61.9%	$14,705	-49.8%	$3,073	-86.5%
Average dollars per deal	$174	-52.2%	$213	-42.6%	$99	-74.8%
Deals of US$1+ billion	2	-71.4%	2	-66.7%	0	-100.0%

Source: Ernst & Young. Combined numbers between US and European entity only count once in this column. Growth is relative to 2008.

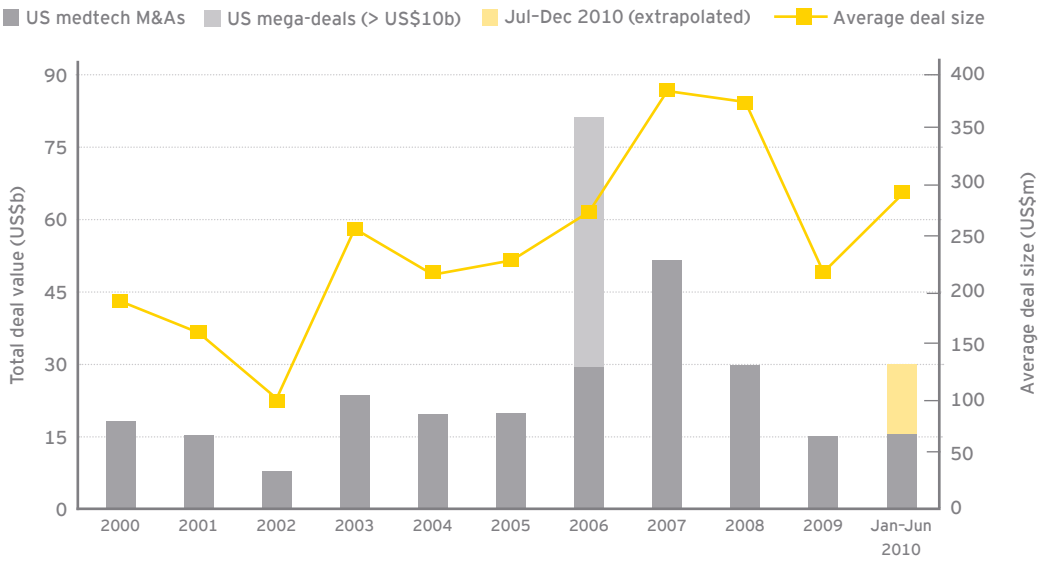
> "Despite very favorable valuations, acquirers are not buying assets just because they are cheap. They are focused on creating value for the long term and understand that a bad deal done cheaply is still a bad deal."

Sharing risk

In addition to seeking medtech targets that have achieved product approval and established commercial operations, strategic acquirers have increasingly used milestone payments and structured earn-outs to help pass some of an acquisition's risk to the seller.

Since the financial crisis hit, the percentage of M&As where a target is purchased "outright" has decreased. Only 11.4% of acquisitions of US$75 million or more that involved private companies contained milestone payments in 2008. In 2009, that number more than doubled to 26.3%, and it has remained at 25.0% through the first half of 2010. Compared to earlier in the decade, the amount of up-front money paid decreased from about 85%–90% of the total potential transaction value to just over 70% in 2010. During the past 18 months, some of the largest transactions with milestones included Medtronic's acquisitions of CoreValve (US$700 million up front; undisclosed milestone payments) and Ablation Frontiers (US$225 million; milestone payments also undisclosed), as well as Abbott's takeover of Evalve (US$320 million up front; plus the potential for US$90 million of additional milestone payments) and Baxter's acquisition of ApaTech (US$240 million up front; plus the potential for US$90 million of additional milestone payments). While this is a development that sellers would obviously like to avoid, we anticipate milestone payments will continue to be employed frequently until sellers gain back some leverage in the M&A market.

US M&As, 2000–H1 2010



Source: Ernst & Young, Capital IQ, BMO Capital Markets and Windhover

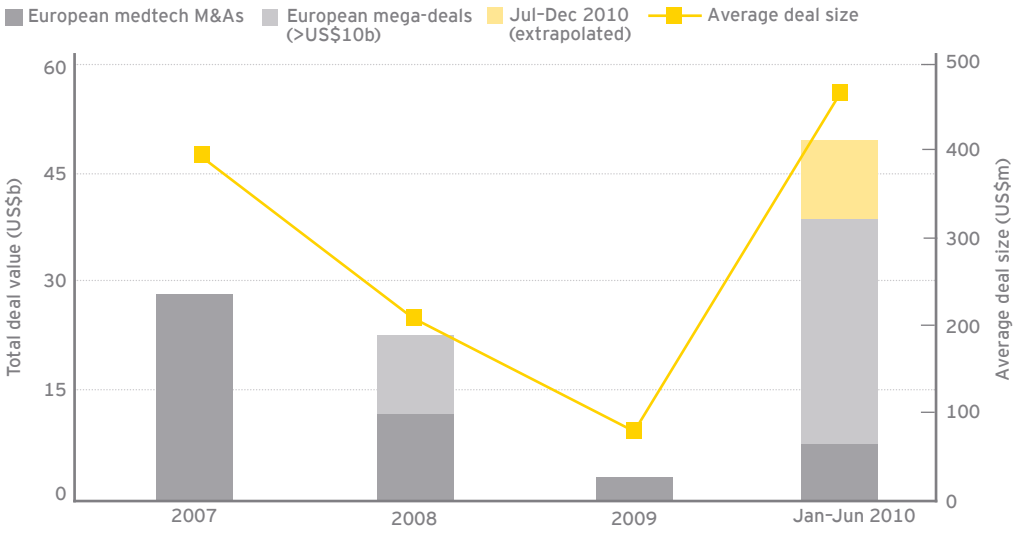
Significant deals

The size and composition of the medtech transactions have evolved over the past decade. While strategic medtechs and conglomerates once dominated the top deals, private equity firms emerged as major players in 2006 and 2007. More recently, pharmaceutical companies have become significant buyers of medtech assets as they seek to diversify into new sources of revenue growth. As the financial crisis ended an era of easy money, we've also seen a shift in the sizes of transactions. In 2007, 15 deals surpassed the US$1 billion mark and 22 exceeded US$500 million. Fast forward to 2009 and those numbers drop to two and eight, respectively. While we have seen some uptick in deal sizes in the first half of 2010, pharma companies remain the largest buyers, with Novartis, Merck KGaA and Abbott accounting for the three largest deals.

Abbott's US$2.9 billion acquisition of Santa Ana, California-based Advanced Medical Optics (AMO), a developer of cataract and laser vision-correction (laser-assisted in situ keratomileusis or LASIK) surgical products, was the largest medtech deal of 2009. While the February 2009 deal gave Abbott a leadership position in the fast-growing ophthalmic business, the company used other acquisitions to diversify its medtech portfolio. In the third quarter of 2009, Abbott acquired the remaining shares of Menlo Park, California-based Evalve that it did not already own for an up-front payment of US$320 million, plus an additional US$90 million in potential milestone payments. The acquisition of Evalve's European-approved MitraClip® system provided Abbott with a leading presence in the growing area of non-surgical treatment for structural heart disease. Later in the quarter, Abbott further expanded its emerging ophthalmic franchise by spending US$400 million for Irvine, California's Visiogen and its Synchrony® artificial lens technology.

> "Only 11.4% of acquisitions of US$75 million or more that involved private companies contained milestone payments in 2008. In 2009, that number more than doubled to 26.3%, and it has remained at 25.0% through the first half of 2010."

European M&As, 2007–H1 2010



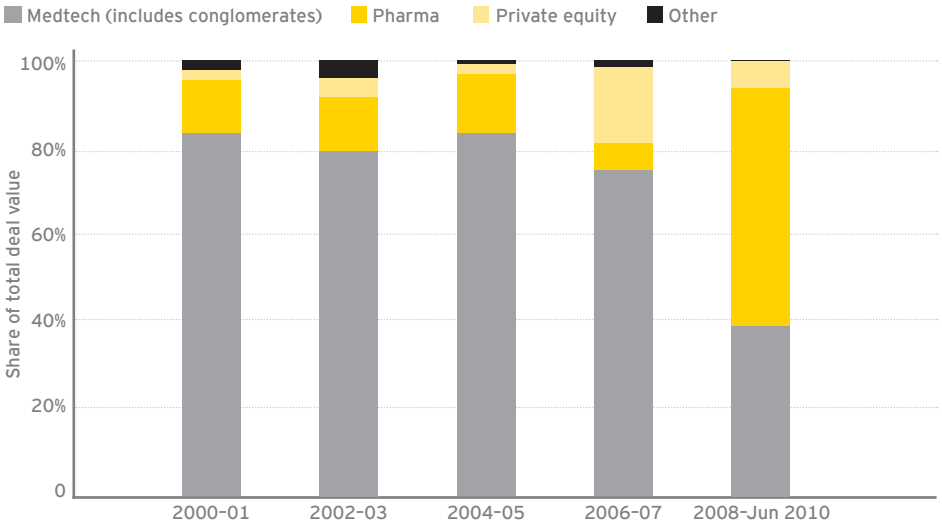
Source: Ernst & Young, Capital IQ. BMO Capital Markets and Windhover

The industry's second-largest deal in 2009 was Agilent Technologies' US$1.5 billion purchase of Varian of Palo Alto, California. The Varian acquisition broadened Agilent's applications and solutions offerings in life sciences by expanding the company into atomic and molecular spectroscopy, as well as strengthening its consumables portfolio. Beckman Coulter's US$800 million deal for Olympus' diagnostic division was the year's third-largest and was followed closely by the US$785 million paid for Menlo Park, California's privately held Acclarent by Johnson & Johnson's Ethicon division in the fourth quarter. The purchase of Acclarent's Balloon Sinuplasty technology and Relieva product portfolio was expected to boost J&J's presence in the ear, nose and throat treatment business. The acquisition marked Ethicon's third sizeable deal in less than 14 months, having acquired Mentor (US$1.1 billion) and Omrix Biopharmaceuticals (US$438 million) in the fourth quarter of 2008.

Danaher Corporation, the Washington, D.C.-based conglomerate, also made waves in the third quarter of 2009 with a pair of deals with Canada's MDS that totaled US$1.1 billion. The company paid US$450 million for MDS's Analytical Technologies division, which included a 50% ownership position in Life Technologies/MDS Sciex joint venture AB SCIEX, a mass spectrometry business; and US$650 million for all of MDS's Molecular Devices Corporation subsidiary, a bioresearch and analytical instrumentation company. But perhaps the most interesting M&A of 2009 was Stryker's US$525 million takeout of Ascent Healthcare Solutions. While Stryker is best known for its orthopedic and surgical products, the addition of Ascent propelled the company into the world of services as it became a market leader in the reprocessing and remanufacturing of medical devices. The rationale for the Ascent transaction was not only to position Stryker as a leader in sustainability but also to enhance its value proposition to hospitals and providers by delivering significant cost savings to the health care system.

The number of notable deals increased markedly in the first half of 2010, including a transaction that looks poised to become the industry's largest deal of all time. In April 2008, Swiss drugmaker Novartis AG agreed to acquire a 25% stake of Alcon, a manufacturer and marketer of vision products, from fellow Swiss company Nestlé for CHF11.1 billion (US$10.5 billion). As we noted in last year's report, Novartis pulled the trigger on Alcon — which had sales of US$6.5 billion in 2009 — to further diversify its business beyond pharmaceuticals. In early January 2010, Novartis exercised its call

Global M&As by type of buyer, 2000–H1 2010
Non-medtech buyers have become increasingly visible



Source: Ernst & Young, Capital IQ. BMO Capital Markets and Windhover

Selected US M&As, 2009–H1 2010

Acquiring company	Location	Acquired company	Location	Value (US$m)
H1 2010				
Merck KGaA	Germany	Millipore	Massachusetts	$7,200
Covidien	Massachusetts	ev3	Minnesota	$2,600
Medtronic	Minnesota	Invatec	Switzerland	$500
Medtronic	Minnesota	ATS Medical	Minnesota	$370
Baxter International	Illinois	ApaTech	United Kingdom	$330
2009				
Abbott	Illinois	Advanced Medical Optics	Southern California	$2,857
Agilent Technologies	Northern California	Varian	Northern California	$1,499
Beckman Coulter	Southern California	Olympus (diagnostic systems)	Japan	$800
Johnson & Johnson (Ethicon)	New Jersey	Acclarent	Northern California	$785
Medtronic	Minnesota	CoreValve	Southern California	$700
Danaher	District of Columbia	MDS (Analytical Technologies)	Canada	$650
Stryker	Michigan	Ascent Healthcare Solutions	Arizona	$525
Sonova	Switzerland	Advanced Bionics	Southern California	$489

Source: Ernst & Young, Capital IQ, Windhover and BMO Capital Markets

Selected European M&As, 2009–H1 2010

Acquiring company	Location	Acquired company	Location	Value (US$m)
H1 2010				
Novartis	Switzerland	Alcon (52% of company)	Switzerland	$28,300
Merck KGaA	Germany	Millipore	US	$7,200
Cinven	United Kingdom	Sebia SA	France	$1,100
Medtronic	US	Invatec	Switzerland	$500
Nordic Capital	Sweden	Handicare	Norway	$460
2009				
Alcon	Switzerland	ESBATech	Switzerland	$589
Sonova	Switzerland	Advanced Bionics	US	$489
Thermo Fisher Scientific	US	Brahms AG	Germany	$470
Medtronic	US	Ventor Technologies	Israel	$325
Alere (formerly Inverness Medical Innovations)	US	Concateno	United Kingdom	$236
Qiagen	Netherlands	DxS	US	$130
Gen-Probe	US	Tepnel Life Sciences	United Kingdom	$132

Source: Ernst & Young, Capital IQ, Windhover and BMO Capital Markets

option to buy an additional 52% stake from Nestlé for US$28.3 billion (for a total of US$38.8 billion), and also announced its intention to gain full ownership of Alcon by entering into an all-stock direct merger for the remaining 23% minority stake. According to Novartis, the combined company's products will cover more than 70% of the global vision care sector. While Novartis closed the transaction for the 77% majority ownership of Alcon from Nestlé in August 2010, as of September, Novartis had still not come to terms with Alcon's independent directors' committee for the remaining 23% of shares. When ultimately completed, the Alcon deal will approach US$50 billion and will easily topple medtech's previous record deal of US$28.4 billion set by Boston Scientific's acquisition of Guidant in 2006.

While the final details for Alcon were being ironed out between Novartis and Nestlé, Alcon continued to be an active acquirer. In the third quarter of 2009, Alcon paid US$150 million to scoop up Switzerland-based ESBATech's antibody fragment eye technology, with US$439 million more reserved for potential milestone payments. In addition to the ESBATech transaction, Alcon acquired Israel's Optonol in the fourth quarter and also inked a pact with AstraZeneca to further investigate new ophthalmic solutions.

Germany-based Merck KGaA's US$7.2 billion takeover of Millipore, the Billerica, Massachusetts-based provider of tests and equipment to the life sciences industry, was the second-largest transaction in the first half of 2010. Merck will use Millipore's capabilities to expand its presence beyond drugs. Overall, some of the most active acquirers in 2009 and the first half of 2010 were Abbott (three deals; US$3.7 billion), Covidien (seven; US$3.6 billion), Danaher (four; US$1.3 billion), Inverness Medical Innovations (now Alere) (four; US$907 million), Medtronic (six; US$2.1 billion) and Thermo Fisher Scientific (six; US$995 million). As was the case in 2008, some traditionally active acquirers, such as Boston Scientific, General Electric, Philips and Siemens, have remained quiet in 2009 and the first half of 2010.

US deals

In 2009, M&A deals involving US-headquartered medtech companies fell to the lowest levels seen since 2002 on multiple fronts: number of deals, total deal values and average deal size. Deal values plunged nearly 50% over the prior year, to US$14.7 billion, while the number of deals and average deal size were down 14% and 43%, respectively. All of these figures were well below the record-setting levels seen in 2006 and 2007. While the high deal activity in those years was attributable at least in part to the era of easy money, it is also true that the appetite of many would-be acquirers fell in 2009 because of lingering concerns about market demand and regulatory and health care reforms.

However, there has been a solid rebound in 2010, as the first half of the year has produced US$15 billion worth of transactions — already surpassing the aggregate value of transactions for all of 2009. Almost half of this figure is the result of Merck KGaA's acquisition of Millipore. Overall, non-imaging diagnostics, research and other equipment and cardiovascular/vascular companies continued to attract the most suitors during the past 18 months.

US transactions by segment, 2009–H1 2010

Segment	Number of deals	Value (US$m)	% of total deal value
Therapeutic devices (all)	57	$12,945	43.8%
Aesthetics	4	$404	1.4%
Cardiovascular/vascular	20	$6,061	20.5%
Ear, nose and throat	4	$1,379	4.7%
Non-disease-specific	4	$616	2.1%
Ophthalmic	3	$3,258	11.0%
Orthopedic	7	$521	1.8%
Research and other equipment	22	$11,518	39.0%
Non-imaging diagnostics	29	$3,624	12.3%
Imaging	4	$186	0.6%
Other	7	$1,292	4.4%

Source: Ernst & Young, Capital IQ, BMO Capital Markets and Windhover
Chart only shows deals where deal values were publicly disclosed.

European deals

While the US M&A market was challenging in 2009, Europe's performance was even worse. European medtech companies were only involved in US$3.0 billion worth of deals in 2009 (down from US$22.8 billion in 2008 and US$28.0 billion in 2007), while the number of deals and average deal size also fell considerably. Conspicuously missing from the deal landscape in 2009 were the types of signature acquisitions that had been consummated in 2007 and 2008 by the likes of industry leaders Siemens, Philips and Fresenius. This lack of activity may be the result of a number of factors, including the companies' focus on enhancing internal operations and the continued digestion of their earlier, significant acquisitions.

The Novartis/Alcon deal ensured that 2010 would not repeat the low levels of 2009. While the US$28.3 billion spent for Nestlé's remaining Alcon shares has certainly overshadowed other transactions, other deals involving European medtechs during the first six months of 2010 totaled more than US$10 billion. Europe's largest deals in early 2010 have been dominated by both pharma companies and private equity firms.

Private equity retrenches and re-emerges

One of the more intriguing stories in transactions this past year has been the slow but steady re-emergence of private equity (PE) as a viable buyer of medtech companies. Armed with large amounts of cash and readily available debt financing, PE firms sparked unprecedented transaction volumes across all industries between 2005 and 2008, including medtech. From 2000 to 2004, PE firms completed 37 medtech transactions for an announced total of US$2.6 billion. Those numbers skyrocketed between 2005 and 2008, to 97 medtech M&As with announced values in excess of US$27 billion. Fueled by a half-dozen US$1 billion-plus transactions, PE houses used a number of different methods to acquire portfolio companies – including take-private transactions, corporate carve-outs and tuck-in/add-on acquisitions – which helped fuel medtech's M&A rally in 2006 and 2007.

European transactions by segment, 2009–H1 2010

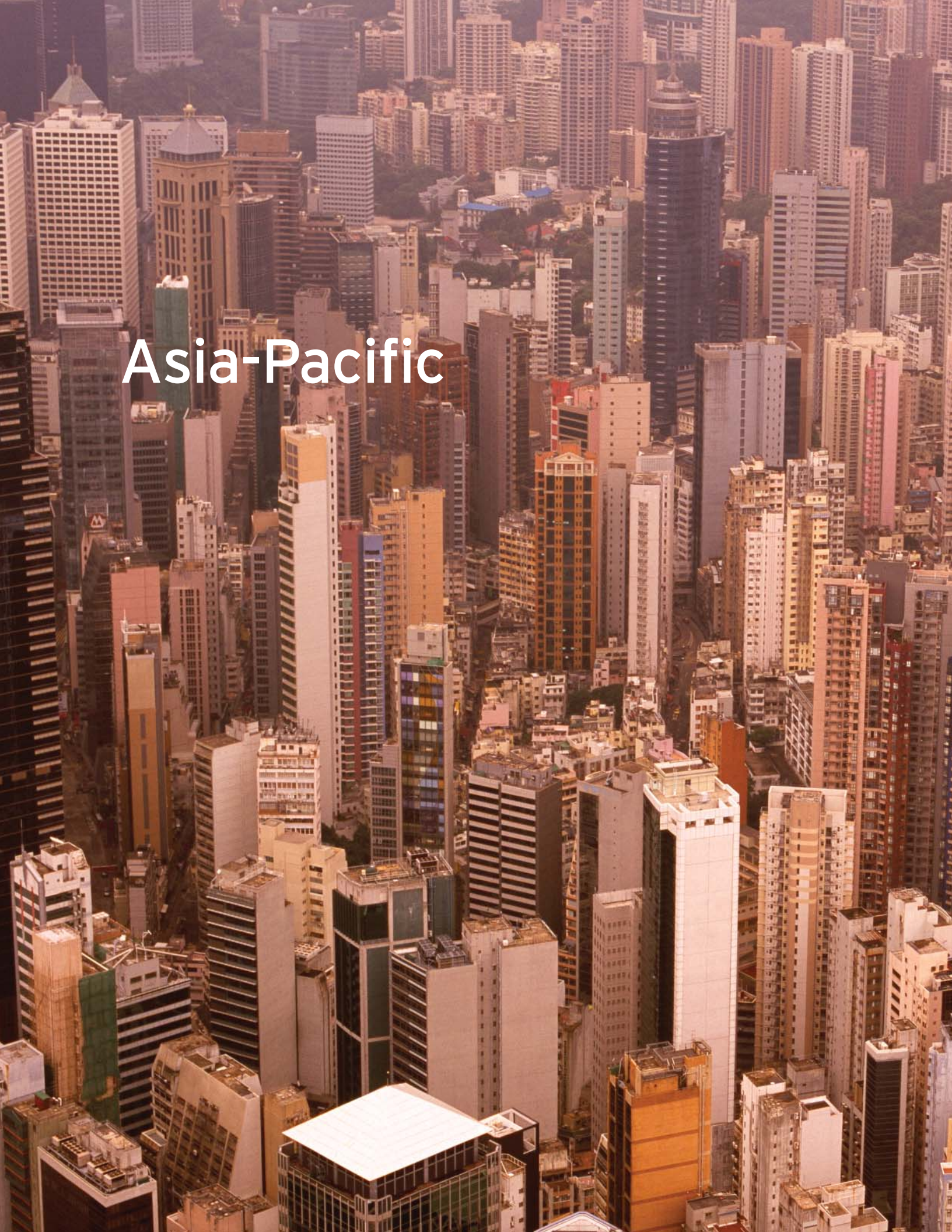
Segment	Number of deals	Value (US$m)	% of total deal value
Therapeutic devices (all)	14	$30,384	72.4%
Aesthetics	2	$318	0.8%
Cardiovascular/vascular	3	$832	2.0%
Ear, nose and throat	2	$569	1.4%
Hematology/renal	2	$204	0.5%
Ophthalmic	2	$28,301	67.8%
Research and other equipment	15	$7,934	19%
Non-imaging diagnostics	16	$2,440	5.8%
Imaging	2	$36	0.1%
Other	6	$1,148	2.7%

Source: Ernst & Young, Capital IQ, BMO Capital Markets and Windhover
Chart only shows deals where deal values were publicly disclosed.

PE firms essentially vanished as buyers of medtech assets during the second half of 2008 as access to borrowings largely dried up. By the time 2009 concluded, PE had acquired only 13 medtech companies. However, as we noted in last year's *Pulse of the industry*, we anticipated that PE firms would retrench and re-emerge with an increase in equity-driven deals in the range of US$500 to US$750 million each. Sure enough, PE firms have returned in the first half of 2010. While the two largest transactions included transfers between two PE firms – Cinven's €800 million (US$1.1 billion) acquisition of France's Sebia SA from UK PE firm Montagu Private Equity, and Nordic Capital's US$460 million takeover of Norway's Handicare from Norwegian fund Herkules Capital – we have also seen increased activity in carve-out transactions. Recent carve-out transactions have included GTCR Golder Rauner's Devicor Medical Products acquiring the breast unit from Johnson & Johnson's Ethicon-Endo Surgery subsidiary; Becton Dickinson's sale of its Ophthalmic Systems unit to RoundTable Healthcare Partners; and Linden's acquisition of Agilent Technologies' Hycor Biomedical.

Outlook

Medical technology remains a transaction-driven industry, and M&As will continue to play a vital role in supporting future innovation and growth. That said, the bar for companies seeking an M&A exit will remain high as long as bargaining power remains with buyers, and this will continue to strain the traditional venture funding model. While we cannot rule out the danger of a double-dip recession, the increased clarity around the impact of health care reform in the US may lead to increased activity in the deal market. In addition, expanded regulatory reforms and subsequent increases in product development costs will place more financial pressures on many medtechs and will likely spur further consolidation. Through the first half of 2010, we have seen both financial and strategic buyers increase their M&A activity, and should large strategic buyers maintain healthy cash balances and continue to enjoy access to affordable credit terms, we believe this trend will continue. ▶



Asia-Pacific

Roundtable on China

One size doesn't fit all

Moderated by
Dave DeMarco, PhD
Ernst & Young LLP
Principal

Immanuel Thangaraj
Essex Woodlands
Health Ventures
Managing Director

John Barrett
Medtronic, Inc.
Vice President, Finance, Asia Pacific

Richard Mao, MD
Johnson & Johnson
Medical Asia Pacific
Senior Director and Head of New Business

As margins and growth rates get further squeezed in Western markets, medical technology companies will increasingly rely on overseas sales to accelerate their future growth. Unlike any other emerging market, China will provide US and European medical technology companies with a tremendous opportunity for expansion. While China's ever-expanding middle-class has driven the first wave of medtech's market development, the Chinese Government's ongoing US$125 billion investment into overhauling the country's health infrastructure will make health care available to the masses and provide foreign medtechs with millions of potential new patients – if the Government has the right strategy and product offerings.

To help us better understand the medtech landscape in China, we sat down with three industry veterans who have first-hand experience of operating in the Middle Kingdom. **Richard Mao**, the panel's lone Chinese national, is responsible for Johnson & Johnson Medical's business development function in the Asia-Pacific region. Also on the panel was **John Barrett**, Vice President of Finance for Medtronic. Based in Tokyo, John has held multiple roles within China and throughout Asia for nearly a decade. Finally, **Immanuel Thangaraj**, Managing Director for the venture firm Essex Woodlands Health Ventures, has an active portfolio of China-based medtechs. The roundtable was moderated by **Dave DeMarco** of Ernst & Young.

The panel's tone is one of immense optimism as China presents magnificent possibilities for the global medtech industry. However, in order to be successful, foreign medtechs must be able to adapt to China's unique culture, languages, business protocols, politics and Government regulations. They'll also need to be knowledgeable of the country's different markets and what drives their purchasing decisions, and be prepared to compete with an increasingly sophisticated homegrown medtech industry.

DeMarco: What rules of the road should medtech organizations know when they establish operations in China? What are the biggest barriers to entry?

Mao: Foreign medtechs need to do their homework before jumping into the Chinese market. China's needs and rules are different from those of developed nations. Companies must have the right product for the right market, and they need to be cognizant of China's unique regulatory and compliance environments.

After companies complete their homework, the next critical step is to establish distribution capabilities with a knowledgeable local partner that can help foreigners address many of the Chinese market's challenges. If a company decides to use an acquisition to enter or expand in the Chinese market, it will need very rigorous due diligence to address local risk factors such as product quality, regulatory approval and talent retention. Buyers would be best served letting the acquired company continue to act as a stand-alone entity – preserving the company name, culture and so on – to ensure a smooth transition and to preserve its value and knowledge.

Barrett: In past years, China was known as the low-cost manufacturing capital of the world. Recently, the Chinese Government has been actively promoting high-value business and the manufacturing capabilities of Chinese firms have moved up the value chain. One of the biggest challenges we face as a foreign multinational is how to distinguish ourselves from the local companies as they come up that value chain.

Thangaraj: So far, Essex Woodlands has only invested in two Chinese companies that were producing revenue at the time of the transaction, and these firms were already profitable. Through this investment strategy, we've been able to partner with local investors and bypass some of the obstacles related to establishing operations from scratch.

That being said, the differences in language and culture are challenges for us. Unlike the Chinese teams at most foreign firms, our investment team doesn't consist of Chinese nationals at this time. So we don't understand all of the cultural aspects of China, which are often significant. To address this issue, many firms hire Chinese professionals, but there are relatively few candidates with solid investment experience and local experience. When we are ready to open an office in China, we either need to find someone with a US knowledge base – such as a Chinese national trained in the US – or we have to build expertise on the ground in China, which takes time.

DeMarco: How should foreign medtechs work with Chinese authorities to ensure a favorable relationship?

Barrett: The Chinese Government has come a long way over the past 20 to 30 years. While Government officials will readily acknowledge that they don't have all the answers to some of the market's problems, they are smart and learn quickly. Government officials are open to partnering with foreign companies. Thus Medtronic, being a global technology leader, has been able to develop a partnership where we've educated them on our therapies and provided feedback on various policy proposals. Regulations can still at times be confusing, but overall, they are very smart people and we've found that it's very beneficial to collaboratively work with them.

DeMarco: The rise of China's middle class and the Government's massive investment in health care present opportunities for medtech companies. How are you targeting these new patient populations?

Mao: Historically, J&J has largely focused on the premium, urban patient market – what we call the "S1 segment." However, an equally important opportunity exists for us in the lower-income, mass market, or the "S2 segment" – a patient group that will begin to enjoy some degree of coverage through health care reform. Since the needs of the S1 and S2 segments are very different, we maintain distinct business models and product mixes for each group. In fact, J&J has established a separate company called "HCS China" that specifically distributes products for the S2 market. J&J also decided to create a Medical Device and Diagnostic R&D center in China that will focus on market-appropriate innovation that enables us to be quicker and efficient and, most importantly, to better understand and satisfy the local needs of patients and physicians.

> "Foreign medtechs need to do their homework before jumping into the Chinese market. China's needs and rules are different from those of developed nations."

Barrett: Medtronic also segments the Chinese market, but we've broken it down into three product tiers – premium, value and low income. "Premium" would be products imported by multinationals with a strong global clinical background. The "value" segment would be high-quality locally produced products. I agree with Richard that foreign medtechs must adapt to the Chinese market. Rather than exclusively selling US- or Europe-developed premium products in China, companies need to adapt and compete with the products being developed locally by local companies. Medtronic has adopted some strategies over the last two years that have worked very well. These have ranged from partnering with local Chinese companies to developing both products and distribution strategies that combine the strengths of each model.

> "Despite progress on this front, there is still a huge shortage of talent at the executive and board level … The mix of skills we have today may not be the right ones to take us to US$500 million or US$1 billion in Chinese sales."

Thangaraj: I also see a trifurcated market in China that consists of the super rich, the middle class and the lower-than-middle class. The late University of Michigan economist CK Prahalad famously noted that big companies can make a lot of money making inexpensive products for large, less-prosperous populations. So while Western multinationals will continue to sell premium devices to the super rich, there's also a huge opportunity to target the ever-expanding middle-class population with products adapted for the local market. As for the lower class, I think local companies are most likely to focus on that group.

DeMarco: In 2008, an Ernst & Young survey identified "human capital" – high employee turnover and lack of homegrown middle management – as one of the biggest obstacles to success in China. What steps have organizations taken to better recruit, manage and retain employees?

Barrett: As a result of Medtronic's heavy investment in talent development, training and education, the issue of turnover has steadily improved over the last five to six years. We've recognized Chinese workers' tremendous thirst for development and education opportunities by developing management and leadership camps. We've also enabled the high-potential employees to have opportunities to speak with our management board and thus ensure that their ideas are shared and that growth opportunities are available across the company. Despite progress on this front, there is still a huge shortage of talent at the executive and board level. As Medtronic has grown from a company with US$100 million in Chinese-based sales to one with more than US$300 million, we've required different types of leaders along the way. The mix of skills we have today may not be the right ones to take us to US$500 million or US$1 billion in Chinese sales. So developing and maintaining strong leadership will remain a challenge in China.

Mao: I can relate to what John is saying. Since J&J's business in China is growing fast, developing the right management and first-line sales team can present a challenge. We advocate the use of local management teams to manage the local business since they are best positioned to understand the specific needs of Chinese customers. We view people as our greatest asset, and we are committed to providing continuous training and career development for our managers. While compensation is obviously very important, we believe talented employees will stay if they see opportunities for personal growth and advancement as the company expands.

DeMarco: How do you manage your product portfolio mix in China?

Thangaraj: MicroPort, one of our Chinese portfolio companies, took advantage of unprotected IP to legally produce a drug-eluting stent based on the design of a leading Western product. Today, MicroPort's stent has equal, if not better, quality, is manufactured at a lower cost and is sold for much less than its Western competitors. As such, it has become the market leader in drug-eluting stents in China, beating out other foreign multinationals that are active in the space. While the super wealthy in China may be willing to pay premium prices for Western products, the majority of patients – who often need to dig into family savings to pay for health care – will more often than not choose a product that delivers comparable care at a fraction of the cost.

Barrett: Market segmentation is critical. I believe there are two components to managing your product portfolio mix in China. First, there is a lot of R&D and clinical research that goes into Medtronic's premium products, so we will always sell those premium products in the China market. The second component is to customize the product specifications for the local market – can the product be simplified

"While the super wealthy in China may be willing to pay premium prices for Western products, the majority of patients – who often need to dig into family savings to pay for health care – will more often than not choose a product that delivers comparable care at a fraction of the cost."

and made cheaper, and, most important, who is going to pay for it? However, it is very hard to customize products in China because the regulatory cycle for these new products is typically two years. By the time we've modified a technology and earned regulatory approval, the technology will have moved on. One of Medtronic's most important priorities is to increase patient access to our therapies, and a key component of being successful in China will be to continue to adapt the product portfolio and take advantage of the capabilities locally to begin developing more and more locally produced products.

DeMarco: How will the Government's expansion of health care coverage impact the future of China's pricing and reimbursement landscape? Will private-pay patients continue to be the primary customers for Western products in China?

Mao: In addition, China's reimbursement system is rather complex and varies from state to state and product to product. With the advent of health care reform, more of the Chinese population will have access to better health care and Government reimbursement will obviously play a bigger role moving forward. From J&J's perspective, our objective is to provide the right products and solutions for patients and physicians, at the right price point.

Barrett: The Chinese Government currently reimburses a portion of certain product costs, and individuals are responsible for paying the rest. While it's true there are a lot of therapies that receive no Government reimbursement, some high-end technologies like coronary stents do, and as a result, the market for stents has absolutely exploded over the past 5 to 10 years.

Government coverage and reimbursement will undoubtedly increase over the next several years. However, I suspect the fortunes of companies in our field will be more positively impacted by the expansion of private health insurance. Private insurance has yet to take off in a big way, and that is one area where we see a huge opportunity for expansion – particularly at the top end of the market. There are many people who have salaries comparable to those in the US or Europe, and they can afford private health insurance. As a result, they'll be able to access the top therapies.

Thangaraj: To sell a medtech product in China, companies need to go through regional tender processes that usually position a Chinese manufacturer against a foreign company. While the Chinese companies usually face greater pricing pressure, they also have greater access to the tender process. No matter who wins the tender, if a company has a good hospital-based product with demonstrated results, I would suspect that it will have a good chance of gaining Government reimbursement. Conversely, it will take some time before Government reimbursement is pervasive enough for companies to focus on selling devices to individual patients. In the interim, many companies will continue to operate on a cash payment system.

"... big companies can make a lot of money making inexpensive products for large, less-prosperous populations. So while Western multinationals will continue to sell premium devices to the super rich, there's also a huge opportunity to target the ever-expanding middle-class population with products adapted for the local market."

"Private insurance has yet to take off in a big way, and that is one area where we see a huge opportunity for expansion – particularly at the top end of the market. There are many people who have salaries comparable to those in the US or Europe, and they can afford private health insurance. As a result, they'll be able to access the top therapies."

DeMarco: How do you manage the potential risks of your vendor supply chain in China? Conversely, how do you manage the risk of distribution to hospitals?

Thangaraj: We found there are cultural factors in the supply chain that we were not accustomed to. Disruptions such as strikes or national holidays can shut down an entire country and cripple your supply chain. Also, while the infrastructure within the country is very good, there is more competition for people, and this has resulted in rising compensation and increasing costs in the supply chain. On the distribution side, we've found it much better to use distributors as opposed to direct sales forces. We've seen multinationals come in and try to engage in sales activities directly with physicians, but they never got good traction.

Mao: Physicians and patients are always our first responsibilities at J&J, and we base our reputations on the value we bring them. Consequently we observe very high medical standards in China and maintain a strict policy to fully comply with the local laws and regulations. We hold the same standards for our business partners, and for this reason, we provide training to ensure they are also fully compliant with local laws and regulations.

DeMarco: How would you rate the level of domestic medtech players, and where do you see the level of competition increasing over the next three to five years?

Barrett: Today, there are many Chinese medtech companies that are well run – highly profitable and well monitored. As was mentioned by Immanuel earlier, some of these companies have gained an advantage by using unprotected IP to produce similar products, and they have then done a very good job of further developing the market with those technologies. These firms have a fantastic ability to manage large sales and distribution networks and manufacturing facilities – and they truly understand how to work with dealers and hospitals.

But their biggest challenge moving forward will be identifying where the next products in their pipelines will come from. While they've been able to differentiate themselves in the past by taking existing technologies and making them better for the local market, multinationals have become much more adept at patenting technologies in China, thus protecting their IP. On the flip side, local companies tend to have much smaller R&D budgets. But the Chinese Government is encouraging local companies to spend more on R&D, and if it decides to directly finance more R&D spending, it could become easier for Chinese medtechs to address their pipeline issues.

Mao: Demand for high-quality, low-cost medical products in China is very strong. As a result, competition from local companies is fierce and the number of players is expanding every day. While local companies may initially enter the market with a specific product, they are very nimble and can quickly move to the next market opportunity – even if it is outside their existing core competencies. In the next three to five years, innovation will be the key differentiator. To succeed, companies – regardless of whether they are multinationals or local medtechs – will need to truly understand the needs of Chinese customers and be flexible enough to quickly develop innovative, market-appropriate products for China.

Thangaraj: I agree with Richard. Chinese medtech companies are extremely innovative and entrepreneurial. While Chinese companies have the capability to deliver Western-style product innovation, they are really succeeding in what Richard termed "market-appropriate" innovation. The Chinese are very good at adapting their products for local consumers, and they're going to continue to develop products that don't have all the features of Western products but are cheaper and still satisfy the needs of local consumers. Over the next few years, expect to see Chinese companies successfully develop low-cost, high-quality innovation models. Expect to see more of them go head-to-head with foreign multinationals in certain premium product segments – both within China and elsewhere. ▶

Increased focus and reforms across Asia-Pacific's medtech markets

While most of the global economy has been mired in a stubborn recession over the past couple of years, several economies in the Asia-Pacific region have bucked the trend with robust growth, and this is reflected in the region's medical technology sector. While the medtech industries of individual economies are in very different stages of development, the advent of multinational players is rapidly transforming the region's medtech industry. Countries such as India, China and South Korea are still at a nascent stage of development due to their small and fragmented markets, heavy dependence on imports of high-end medical devices and unclear regulatory norms. On the other hand, Japan and Australia have more well-established medtech markets, with significant local players and relatively transparent regulatory frameworks.

Multinational companies are devising country-specific investment and growth strategies to expand their market reach. However, private equity and venture capital investment activity remains low in most countries. India and China are becoming preferred manufacturing hubs for driving operational efficiencies, especially for less complex devices, while in other countries, such as Japan, Australia and South Korea, global players seek potential licensing or M&A opportunities to increase their market reach. Meanwhile, local domestic companies — often boosted by government support and investments from foreign players — are looking to play a larger role in the future.

Japan

Japan's medical technology market is the second-largest in the world, behind only the US. The country boasts capabilities in the manufacture of diagnostic-imaging equipment, surgical equipment, biophenomena measuring and monitoring systems, and home therapeutic equipment. Despite these strengths, the sector remains heavily dependent on imports.

Regulatory reform

Japan's health care system provides universal coverage. Medical device manufacturers have often expressed frustration with the overall regulatory protocol and slow approval timelines. To address this issue, the Ministry of Health, Labor and Welfare, the agency responsible for the regulation and payment of medical devices, launched a five-year plan, effective 1 April 2009, to streamline the regulatory review process and increase the number of reviewers from 35 to 104 over a period of five years.

Japanese companies invest overseas
In recent years, leading Japanese firms, such as Nipro, Olympus Medical Systems, Toshiba Medical Systems, Hitachi Medico and Asahi Kasei Kuraray Medical, have been increasingly active in international markets by expanding overseas manufacturing, as well as engaging in acquisitions.

In May 2010, Nipro announced plans to invest nearly US$110 million to set up an artificial kidney plant in India. The company expects to cut manufacturing costs by as much as 50% through this investment. In addition, the company is investing approximately US$66 million to triple its manufacturing capacity of cardiopulmonary oxygenators in Brazil by 2011. Asahi Kasei Kuraray Medical Co. also announced plans to expand overseas production of artificial kidneys – specifically for the Chinese and European markets. In November 2009, the company launched a South Korean subsidiary to market its artificial kidneys, hemocatharsis devices and related products in South Korea.

Notable M&A transactions include Olympus Corp.'s June 2010 acquisition of US-based Spiration. As noted in the M&A article, Olympus was also active on the sell side as the company sold its diagnostics unit to Beckman Coulter in 2009. Nipro completed the acquisition of Home Diagnostics Inc., a US company engaged in the manufacture of home-use blood glucose monitoring systems, for US$215 million.

Accessing the Japanese market
The size of the Japanese market remains an attractive prospect for foreign companies, with a number of US and European companies entering strategic alliances to increase their access to Japanese customers. Examples include US-based radiation-therapy company TomoTherapy (which partnered with Hitachi Medical Corp. to sell its Hi-Art cancer treatment in Japan) and Germany-based Fresenius Medical Care (which signed a 10-year agreement with Nikkiso to market its hemodialysis and peritoneal dialysis products in Japan). Meanwhile, US-based Masimo signed a technology licensing agreement in June 2010 with Fukuda Denshi, a local manufacturer of electronic medical devices, to integrate its Rainbow SET Pulse CO-Oximetry technology into Fukuda Denshi's next generation patient monitors.

China

The Chinese medical device market is estimated to be the sixth-largest in the world. It is also one of the fastest-growing. China largely produces and exports low-value disposable products, such as consumables and medical dressings, while foreign players control nearly 90% of the high-end medical device market.

Regulatory reform

The Government of China, through its Healthy China 2020 health care reform plan, is investing heavily to ramp up the country's health care infrastructure and implement a new set of health insurance programs with the objective of covering 90% of the country's population by the end of this year. The Government is also promoting the domestic medtech industry by offering subsidies to hospitals that purchase locally produced low-cost medical devices.

To promote the sector, the Government is also working to upgrade existing regulations, revise provisions on device registration, improve testing standards and accelerate approval processes. In March 2010, China's State Food and Drug Administration (SFDA) launched a new center, the Management Center for Medical Device Standards, which aims to rationalize the country's regulatory procedures for medical devices. In December 2009, the SFDA also increased the requirement that device manufacturers register products in the country of export before seeking registration in China. Moreover, devices demonstrating compliance with international standards will no longer need to undergo tests in Chinese labs prior to approval. However, in 2009, the Ministry of Health restricted purchases of high-priced "Group A" medical devices that cost more than 5 million RMB (US$710,000), which could be a potential hurdle for companies that plan to sell large capital medical equipment in China.

A manufacturing hub

Multinational players are expanding their production bases in China to capitalize on burgeoning demand from both local and international markets. In May 2010, UK-based Smith & Nephew announced the completion of its US$100 million medical device manufacturing plant located in the Beijing Yizhuang Economic and Development Zone. In December 2009, Japan's Asahi Kasei Kuraray Medical Co. announced its plans to manufacture dialysis machines at its Chinese manufacturing facility. In the same month, Hitachi Medical Corp. decided to invest nearly US$30 million for manufacturing low-priced image analysis

systems, such as MRI systems, ultrasound diagnostic equipment and x-ray machines, at its Chinese subsidiary. The company intends to double its production capacity at this facility in fiscal year 2010. In October 2009, 3M Company began production at its new medical equipment facility in China. The US$44 million facility will manufacture medical devices in dentistry, orthodontics, epidemiology and dermatology.

Foreign investments

Foreign companies and investors are seeking partnerships and JVs with local firms to expand their market reach. These deals can give foreign firms ways to access rural markets and improve their sales channels. In July 2010, Zimmer Holdings announced that it was acquiring Beijing Montagne Medical Device Co., Ltd. – a manufacturer of artificial joints – in a US$51.7 million deal that allows the US firm to expand its business operations in the country. Another Chinese firm, Dehaier Medical Systems, signed two exclusive distribution agreements recently – one with UK-based Penlon Ltd. for its Prima SP anesthesia system and the other with Germany-based Heyer Medical for its Cumulus ultrasonic nebulizer. In December 2007, Medtronic and China-based Shandong Weigao Group set up a JV, Medtronic Weigao Orthopedica Device Co. Ltd., to jointly develop and market orthopedic devices, such as Medtronic's spine products and Weigao's spine, joint and trauma products.

In April 2010, local firm Beijing Yicheng Bioelectronics Co. Ltd., an important player in China's blood glucose monitor market, raised US$10.3 million in private equity funding from US-based Sequoia Capital and Japan-based PreIPO Capital Partners. The company plans to use this funding to boost its R&D activity and expand its distribution network across the country.

Taiwan

Despite being a high-income market with world-leading technology firms, a strong health care system and universal health insurance coverage, Taiwan does not have a medtech sector that reflects its strengths. The sector has traditionally been dominated by companies producing low-end equipment and has been hobbled by regulatory and reimbursement policies that do not promote innovation.

But has been some progress in recent years. The sector has gradually strengthened its capabilities in the manufacture of orthopedic and implantable products, dental products and contact lenses. Meanwhile, Taiwanese electronics firms are looking

to leverage their technology and R&D strengths to tap the growth potential in segments such as electromedical products. Despite this progress, Taiwan's medtech demand remains dominated by imports, with the US being the leading supplier, followed by Japan and the European Union (EU).

Regulatory and reimbursement reform

Medical device regulation in Taiwan has long been considered one of the most bureaucratic and complicated in Asia. However, the registration and approval process for low-risk medical devices has improved recently. Registration processes that previously required extensive documentation have now been simplified for medical devices already approved in the US and the EU.

The reimbursement of medical devices continues to pose a significant challenge for foreign firms looking to sell high-end products in the Taiwanese market. The Bureau of National Health Insurance's pricing criteria currently specify a single purchase price for all medical devices that treat the same indication. As a result, lower-quality medical devices are effectively subsidized, while high-end medical devices are reimbursed inadequately.

Clusters and parks

In 2009, the Government set up two biomedical clusters – the Hsinchu Biomedical Science Park in northern Taiwan and the Southern Taiwan Science Park. The Hsinchu Biomedical Science Park is expected to focus on developing sophisticated high-end medical devices in collaboration with leading semiconductor and communications manufacturers. The Southern Taiwan Science Park aims to boost the manufacture of medical devices for dental, orthopedic and plastic-surgery applications.

In addition, the Government is planning to establish the Biotechnology Medical Equipment Industry Center (BMEIC) in Kaohsiung Science Park for the development of orthopedics and medical alloy applications products.

Australia

Like its counterparts in the US and Western Europe, the Australian medical device industry comprises diverse companies ranging from small start-ups to large global manufacturers. Large firms such as Cochlear, which is the world leader in cochlear implants, and ResMed, which manufactures devices used to treat sleep apnea, dominate the domestic industry.

Regulatory reforms

The Government of Australia has been taking steps to rationalize the dynamics of the country's health care and medical device industries. The Government implemented a reform agenda to update existing regulations in early 2010. The most noteworthy change is the introduction of a new risk-based review of in vitro diagnostic devices that now need to undergo extensive premarket scrutiny before being marketed in Australia.

The Australian legislation is also strengthening the Government's ability to monitor device-manufacturing plants. In April 2009, a new bill was passed requiring medical device manufacturers with multiple manufacturing facilities in different locations to register each site individually.

Active deal space

Cochlear and ResMed have been very active on the deal front in recent months. In 2009, ResMed acquired two companies: France-based Laboratoires Narval, which produces and distributes a mandibular repositioning device that provides solutions for snoring, and India-based Respicure Medsys, a supplier of critical-care non-invasive ventilation equipment and equipment for the diagnosis and treatment of obstructive sleep apnea. Meanwhile, Cochlear has also signed an exclusive licensing agreement with US-based Otologics LLC for US$25 million to utilize Otologics' technology to develop a cochlear implant with no external parts.

Other domestic companies are also seeking licensing opportunities and substantial investments from potential investors to fuel growth. In June 2010, CathRx Ltd. signed an agreement with Germany-based Pioneer Medical Devices for the manufacture and supply of electrophysiology catheter devices and components across the EU. Another domestic player, Medigard Ltd., signed a five-year agreement with an undisclosed US-based medical device firm in December 2009 for the manufacture and distribution of its patented blood collection device in the US and Canada.

South Korea

The medical device industry in South Korea is expected to sustain double-digit growth with rising demand from Korean hospitals for imported technology-intensive medical devices. The country has the capability to manufacture disposables, basic medical instruments and high-technology equipment, particularly in the area of diagnostic imaging. Nonetheless, the market is still heavily reliant on imports.

To boost domestic manufacturers, the Government announced plans to invest approximately US$861 million in 2008 for the development of novel biological medicines and medical devices. In August 2009, the Government selected two provincial cities, Osong and Daegu, to set up high-tech medical-industrial clusters.

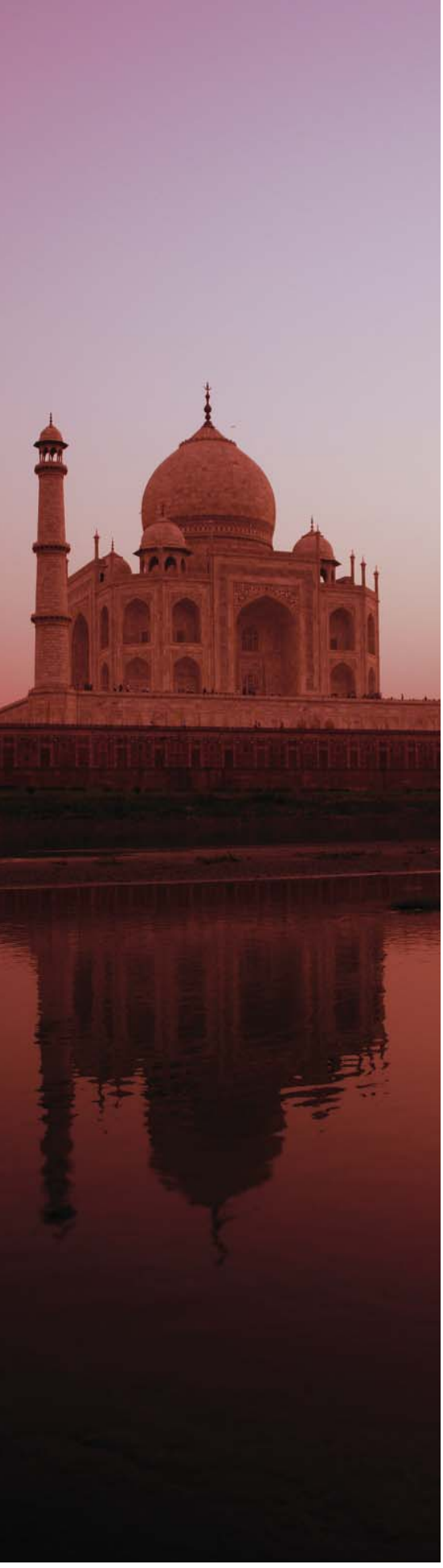
Regulatory and payment reform

The Korean regulatory system for medical devices has often been regarded by industry as opaque. However, the situation has improved since the signing of a free-trade agreement with the US in 2007, which calls for more transparency in the regulation and reimbursement of medical devices.

Effective mid-2009, the Korea Food and Drug Administration (KFDA) – the agency responsible for the public safety of food, drugs and medical devices in the country – eliminated the requirement that companies must seek prior approval from their home countries before applying for approval in South Korea. To make the product-approval process more efficient, the KFDA also began implementing a new risk-classification system on 1 July 2009. The new system has classified 2,000 medical devices into four risk classes, including low-risk medical devices that do not require the submission of technical files, similar to the 510(k) process in the US for Class I devices.

The regulatory reforms have been accompanied by positive developments on product pricing. Previously, regulations in the country required new products to be launched at lower-than-existing market prices unless the product demonstrated significant improvements over existing devices. However, from mid-2009, these regulations have been revised, and prices of novel medical devices offering improved clinical outcomes can now be increased up to 50% over prices of similar existing products.

In an effort to further improve its reimbursement policies, the Ministry of Health and Welfare announced its plans to introduce a new system for the re-



evaluation of medical device reimbursement prices, under which nearly 13,000 medical devices are expected to be divided into three groups that will undergo price re-evaluation triennially.

Notable investments

Several foreign medical device manufacturers are expanding their Korean presence by setting up local facilities, launching new products and acquiring and/or forming alliances with Korean companies. In December 2009, GE Healthcare announced plans to invest close to US$42 million to develop a medical R&D center. Fresenius Medical Care acquired the dialysis business subsidiary of Japan-based Nikkiso Co. Ltd. to strengthen its leadership in South Korea's dialysis market. In June 2010, South Korea's own Samsung Electronics, the world's top electronics firm, made further inroads into the domestic medical device market by launching an ultra-fast blood-testing device that checks the level of glucose, cholesterol and 17 other substances in the blood.

Licensing and distribution alliances are also pursued by foreign companies to enter the market. In June 2009, US-based medical device company Echo Therapeutics entered a licensing agreement with Handok Pharmaceuticals under which the Korean company will develop and sell Echo's Symphony™ tCGM System for transdermal continuous glucose monitoring in South Korea.

India

India's medtech industry has continued to grow, even in the global economic downturn, driven primarily by the cardiovascular and orthopedic devices segment. As in many Asian countries, domestic players dominate the market for low-end devices while multinational companies monopolize the market for high-end products. While the Government is taking steps to boost the health care sector, India's per capita spending on health care remains low, and health care insurance is only available to limited sections of the population.

Regulatory reform

Unlike most markets around the world, India does not comprehensively regulate the safety and efficacy of medical devices. Instead, the Department of Health regulates medical devices under provisions of the Drugs and Cosmetics Act, 1940, and subsequent amendments. The Government has set out to remedy this situation by introducing new legislation, the Central Devices Act, in 2009. This legislation would establish a new regulatory authority

charged with establishing standards and regulating the safety and effectiveness of medical devices manufactured and used in India. Low-end devices would be self-regulated, while a regulatory body would regulate and certify higher-risk devices. In addition, the bill expands the definition of "medical device" in accordance with the medical dictionary, effectively bringing many devices that were previously not regulated under the purview of the law.

The Government has also recently taken steps to promote domestic manufacturers. The 2010 Union Budget exempts specified inputs used for the manufacture of orthopedic implants from import duties. This is expected to increase the competitiveness of locally manufactured orthopedic implants and medical equipment.

Continuing investment

India's comparative strengths — low-cost manufacturing and a pool of skilled engineers and technologists — have become even more attractive in the current economic environment. Not surprisingly, several companies perceive India as a potential manufacturing and development hub, which has prompted many foreign (and even domestic) companies to boost their presence in the country.

Japan's Olympus Corporation opened an Indian subsidiary in April 2010, and Chinese health care group Golden Meditech Company Ltd. also announced plans to enter the market. In 2010, GE Healthcare invested nearly US$50 million to establish an R&D facility in Bengaluru for the design and manufacture of modern molecular imaging systems used in the diagnosis of cancer, heart diseases and brain disorders. The company claims that products manufactured at this facility will be about 30%–40% less expensive than those made elsewhere. Manufacturing in India should get an additional boost from Chennai-based Trivitron Healthcare's investment in India's first-ever medical technology park in Chennai to position India as an alternate and viable low-cost manufacturing site comparable to China.

In addition, various companies are investing in India as an R&D location. Siemens AG has made India a major hub for its R&D of medical diagnostic tools. And Philips has launched the Philips Innovation Center in Bengaluru's software technology park for the development of high-end medical equipment. ▶

Scope of this report

Defining medical technology

In this report, medical technology (medtech) companies are defined as companies that primarily design and manufacture medical technology equipment and supplies and are headquartered within the United States or Europe. For the purposes of this report, we have placed Israel's data and analysis within the European market, and any grouping of the US and Europe has been referred to as "global." This wide-ranging definition includes medical device, diagnostic, drug delivery and analytical/life science tool companies but excludes distributors and service providers such as contract research organizations or contract manufacturing organizations.

By any measure, medical technology is an extraordinarily diverse industry. Medtech companies run the gamut from venture-backed, pre-revenue start-ups to mature global conglomerates. The products of these companies range from relatively inexpensive components to complex, multimillion-dollar magnetic resonance imaging (MRI) systems. Any meaningful analysis of the industry must therefore measure performance not only across the entire industry but also within individual segments.

While developing a consistent and meaningful classification system is important, it is anything but straightforward. Existing taxonomies sometimes segregate companies into scores of thinly populated categories, making it difficult to identify and analyze industry trends. Furthermore, they tend to combine categories based on products (such as imaging or tools) with those based on diseases targeted by those products (such as cardiovascular or oncology), which makes it harder to analyze trends consistently across either dimension.

To address some of these challenges, we have categorized medtech companies across both dimensions — products and diseases targeted. All publicly traded medtech companies were classified as belonging to one of five broad product groups:

- **Imaging:** companies developing products used to diagnose or monitor conditions via imaging technologies, including products such as MRI machines, computed tomography (CT) and X-ray imaging and optical biopsy systems.
- **Non-imaging diagnostics:** companies developing products used to diagnose or monitor conditions via non-imaging technologies, which can include patient monitoring and in vitro testing equipment.
- **Research and other equipment:** companies developing equipment used for research or other purposes, including analytical and life science tools, specialized laboratory equipment and furniture.
- **Therapeutic devices:** companies developing products used to treat patients, including therapeutic medical devices, tools or drug delivery/infusion technologies.
- **Other:** companies developing products that do not fit in any of these categories were classified in this segment.

In addition to product groups, this report tracks conglomerate companies that derive a significant part of their revenues from medical technologies. While a conglomerate medtech division's technology could technically fall into one of the product groups listed above (e.g., General Electric into "imaging" and Allergan into "therapeutic devices"), all conglomerate data is kept separate from that of the non-conglomerates. This is due to the fact that, while conglomerates report revenues for their medtech divisions, they typically do not report other financial results for their medtech divisions, such as research and development or net income. ▶

Conglomerate companies:

United States

- 3M Health Care
- Abbott Diagnostics & Vascular
- Agilent Technologies: Life Sciences
- Allergan: Medical Devices
- Baxter: Medical Delivery & Renal
- Corning Life Sciences
- Danaher: Medical Technologies
- GE Healthcare
- Genzyme: Biosurgery
- Hospira: Medication Management Systems and other devices
- Johnson & Johnson Medical Devices & Diagnostics
- Kimberly-Clark Health Care
- Pall Life Sciences
- Teleflex Medical

Europe

- Agfa-Gevaert
- Beiersdorf: Hansaplast
- Carl Zeiss Meditec
- Dräger Medical
- Philips Healthcare
- Roche Diagnostics
- Siemens Healthcare
- Smiths Medical

Acknowledgements

Project leadership

Gautam Jaggi and **Glen Giovannetti** once again acted as co-editors-in-chief for *Pulse of the industry*. Their strategic and thematic guidance was invaluable in the production of this report, and they ensured that its entire content was clear and concise and properly touched upon each of the major themes impacting the industry. Gautam also authored "The value of innovation" introductory article.

As the project manager for *Pulse of the industry*, **Jason Hillenbach** had responsibility for the entire content and quality of this publication. He was also accountable for the collection and analysis of much of the report's data and was the researcher and writer of the three primary articles within the "Industry performance" section. In addition, Jason conducted most of the interviews for, and was the editor of, the "Innovating innovation," "Dealing with challenges" and "One size doesn't fit all" panels.

Strategic direction

Special thanks to **John Babitt, Carolyn Buck-Luce, Heinrich Christen** and **Dave DeMarco,** who all played key roles in the development of this report. Each provided invaluable insights and first-hand experience that was used as the foundation for the report's key themes and focus. In particular, John brought his years of industry experience to the identification and analysis of industry trends, as well as his diverse contact base to help recruit many of our panelists.

Data analysis

Eric Duhaime co-managed nearly every aspect of this report, from data collection and analysis to research and strategic insights. **Ulrike Trauth** and **Nina Hahn** led and managed the data collection and analysis for the European financial results and financing sections of the report.

Susan Jones and **Kim Medland** helped with the fact-checking and quality review of the data throughout the publication.

Additional writing and editing assistance

Numerous contributors helped draft and write articles throughout *Pulse of the industry*. **Venson Walling** used his firsthand knowledge of the US hospital marketplace to write the "US hospitals: dealing with health care reform" article, while **Chris Ohmes** authored the piece entitled "The uncertain incidence of the medical device excise tax." **Aditya Bhargava** researched and wrote the "Increased focus and reforms across Asia-Pacific's medtech markets" article. Aditya's efforts enabled us to expand the report's scope to the Asia-Pacific region for the very first time.

Susan Jones assisted with the editing of several interviews for our panels.

Russell Colton brought his incomparable skills as a copy editor and proofreader to this publication. His patience, hard work and attention to detail were unparalleled.

Design

This publication would not look the way it does without the diligence and creativity of **George Stainback**. As lead designer, George was responsible for managing and implementing the publication's design and layout.

Marketing and support

Public relations efforts related to the book and its launch were led by **Samantha Sims.** The PR firm of **Feinstein Kean Healthcare** served as an integral partner as well.

Data exhibit index

US exchange rate

	H1 2010	2009	2008
Euro zone	.7550	.7192	.6799

Global medical technology contacts

Global Life Sciences Center	**Boston**	Glen Giovannetti	glen.giovannetti@ey.com	+1 617 585 1998
		Connie Austin	connie.austin@ey.com	+1 617 585 1912
		Gautam Jaggi	gautam.jaggi@ey.com	+1 617 585 3509
		Jason Hillenbach	jason.hillenbach@ey.com	+1 617 375 1244
	New York/New Jersey	Carolyn Buck Luce	carolyn.buck-luce@ey.com	+1 212 773 6450
	Zurich	Patrick Flochel	patrick.flochel@ch.ey.com	+41 58 286 4148
Australia	**Brisbane**	Winna Brown	winna.brown@au.ey.com	+61 7 3011 3343
	Melbourne	Don Brumley	don.brumley@au.ey.com	+61 3 9288 8340
	Sydney	Gamini Martinus	gamini.martinus@au.ey.com	+61 2 9248 4702
Belgium	**Brussels**	Thomas Sileghem	thomas.sileghem@be.ey.com	+32 2 774 9536
Canada	**Montreal**	Paul Karamanoukian	paul.karamanoukian@ca.ey.com	+1 514 874 4307
China	**Beijing**	Stan Chang	stan.chang@cn.ey.com	+86 105 815 3628
		Cherrie Che	cherrie.che@cn.ey.com	+86 105 815 3533
Denmark	**Copenhagen**	Benny Lynge Sørensen	Benny-Lynge.Soerensen@dk.ey.com	+45 358 72525
France	**Paris**	Pascale Augé	pascale.auge@fr.ey.com	+33 1 46 93 77 23
Germany	**Mannheim**	Siegfried Bialojan	siegfried.bialojan@de.ey.com	+49 621 4208 11405
India	**Mumbai**	Hitesh Sharma	hitesh.sharma@in.ey.com	+91 22 6665 5000
		Murali Nair	murali.nair@in.ey.com	+91 22 4035 6300
Israel	**Tel Aviv**	Yoram Wilamowski	yoram.wilamowski@il.ey.com	+972 362 32519
Italy	**Milan**	Lapo Ercoli	lapo.ercoli@it.ey.com	+39 02 7221 2546
Japan	**Tokyo**	Hironao Yazaki	yazaki-hrn@shinnihon.or.jp	+81 3 3503 2165
Netherlands	**Amsterdam**	Jules Verhagen	jules.verhagen@nl.ey.com	+31 88 40 71888
New Zealand	**Auckland**	Jon Hooper	jon.hooper@nz.ey.com	+64 9 375 2670
		Mike Rudd	mike.rudd@nz.ey.com	+64 9 300 8202
Norway	**Trondheim**	Willy Eidissen	willy.eidissen@no.ey.com	+47 73 54 68 80
Russia	**Moscow**	Dmitry Khalilov	dmitry.khalilov@ru.ey.com	+7 495 755 9757
Singapore	**Singapore**	Swee Ho Tan	swee.ho.tan@sg.ey.com	+65 6309 8238
		Shu Han Audrey Chia	audrey.chia@sg.ey.com	+65 6309 8031
South Korea	**Seoul**	Bon Gwang Koo	bon-gwang.koo@kr.ey.com	+82 2 3787 6333
Spain	**Madrid**	Manuel Giralt Herrero	manuel.giraltherrero@es.ey.com	+34 91 572 7479
Sweden	**Uppsala**	Björn Ohlsson	bjorn.ohlsson.uppsala@se.ey.com	+46 18 19 42 22
Switzerland	**Zurich**	Heinrich Christen	heinrich.christen@ch.ey.com	+41 58 286 3485
	Basel	Jürg Zürcher	juerg.zuercher@ch.ey.com	+41 58 286 8403

United Kingdom	**London**	Les Clifford	lclifford@uk.ey.com	+44 20 7951 8600
	Reading	Ian Oliver	ioliver@uk.ey.com	+44 1189 281197
United States	**Boston**	Kevin Casey	kevin.casey1@ey.com	+1 617 585 1817
		Michael Donovan	michael.donovan@ey.com	+1 617 585 1957
		Joseph Bruno	joseph.bruno@ey.com	+1 617 585 1944
	Chicago	Jo Ellen Helmer	joellen.helmer@ey.com	+1 312 879 5262
	Houston	Carole Faig	carole.faig@ey.com	+1 713 750 1535
	Irvine/Orange County	Dave Copley	david.copley@ey.com	+1 949 437 0250
		Kim Letch	kim.letch@ey.com	+1 949 437 0244
	Minneapolis	Ajay Gupta	ajay.gupta@ey.com	+1 612 371 8325
		Bill Miller	william.miller@ey.com	+1 612 371 6984
	New York/New Jersey	Dave DeMarco	dave.demarco@ey.com	+1 732 516 4602
		John Babitt	john.babitt@ey.com	+1 212 773 0912
	Philadephia	Amy Dorfmeister	amy.dorfmeister@ey.com	+1 215 448 5550
		Steve Simpson	stephen.simpson@ey.com	+1 215 448 5309
	Raleigh	Michael Constantino	michael.constantino@ey.com	+1 919 981 2802
	San Diego	Dan Kleeburg	daniel.kleeburg@ey.com	+1 858 535 7209
	San Francisco Bay Area	Chris Nolet	chris.nolet@ey.com	+1 650 496 1620
		Richard Ramko	richard.ramko@ey.com	+1 650 496 4579
		Scott Morrison	scott.morrison@ey.com	+1 650 496 4688

Ernst & Young

Assurance | Tax | Transactions | Advisory

About Ernst & Young
Ernst & Young is a global leader in assurance, tax, transaction and advisory services. Worldwide, our 144,000 people are united by our shared values and an unwavering commitment to quality. We make a difference by helping our people, our clients and our wider communities achieve their potential.

Ernst & Young refers to the global organization of member firms of Ernst & Young Global Limited, each of which is a separate legal entity. Ernst & Young Global Limited, a UK company limited by guarantee, does not provide services to clients. For more information about our organization, please visit www.ey.com.

EYG no. FN0005

CSG NY 1006-1169768

Ernst & Young is committed to reducing its impact on the environment. This document has been printed using recycled paper and vegetable-based ink.