To our clients and friends,

Ernst & Young is pleased to present our second annual report on the state of the medical technology industry. Last year’s inaugural *Pulse of the industry* focused exclusively on the medtech industry within the United States. In this edition of *Pulse*, we have expanded both the depth and the breadth of the report. In addition to tracking the financial, financing and transaction activity within the US, we have broadened our scope to include the European and Israeli medtech markets. This year’s report also includes contributions from the CEOs of the leading medtech industry organizations, Stephen Ubl of AdvaMed and John Wilkinson of Eucomed, as well as tremendous insights from a host of industry insiders on two distinct panels – one composed of CEOs discussing general industry trends and the other discussing the current and future deal-making environment.

Since last year’s *Pulse of the industry* was published, we have experienced the worst global recession since the Great Depression. From Boston to Basel, from financial services to technology, there was barely a geography or an industry that wasn’t negatively affected by the financial crisis. While not totally immune to the downturn of the broader economy – especially in the area of financing and transactions – medtech has emerged from the worst of this period relatively healthy.

While a combination of volatile financial markets, the uncertainty of healthcare reform in the US and other global markets, and a series of other challenges confront the medical technology industry, our report reflects a tone of cautious optimism. Medtech is an industry built on creativity and innovation – both technological and financial – and its fundamental drivers for long-term growth remain strong. The industry has suffered difficult financing periods in the past, but each time, entrepreneurs, investors and companies have adjusted strategies and business models in order to develop cutting-edge technologies that save and improve lives, as well as create cost savings to the healthcare system. It is this type of ingenuity that will enable medtech companies to persevere through these tumultuous times.

Ernst & Young’s global organization stands ready to help you as you navigate these challenges.

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

2  The certainty of innovation  
   Introduction

6  A bullish outlook for US medical technology  
   US industry perspective
   Stephen J. Ubl, AdvaMed

7  Innovation is the key for Europe’s medtech industry  
   European industry perspective
   John Wilkinson, Eucomed

8  Change brings new opportunities  
   CEO roundtable
   - Dan Lemaitre, CoreValve, Inc. (Medtronic)
   - Rick Randall, Trans1, Inc.
   - Ron Sparks, Navilyst Medical, Inc.
   - Dr. H.C. Willy Michel, Ypsomed Holding AG

12 What a difference a year makes  
   Leading indicators

14 US hospitals under pressure  
   US hospital perspective
   Debra McReavy, Ernst & Young LLP

15 Venture capitalists speak out  
   Venture capital perspective

16 A diverse industry  
   Industry segmentation

18 Surviving the squeeze  
   Financial results

26 Here comes the sun: are medtech companies prepared for the Sunshine Act?  
   A closer look

27 A new reality  
   Financing

34 Alternative financing – government incentives  
   A closer look

39 Israel leads venture funding in Europe  
   A closer look

40 Deal-making in uncertain times  
   Transactions roundtable
   - Aileen Stockburger, Johnson & Johnson, Inc.
   - Amy Wendell, Covidien plc
   - Chad Cornell, Medtronic, Inc.
   - Dean Mihas, GTCR Golder Rauner, LLC
   - John Salveson, Piper Jaffrey & Co.

45 Seeking value  
   Transactions

54 New accounting rules impact M&A  
   A closer look

55 Defining medical technology  
   Scope of this report

56 Acknowledgements

57 Data exhibit index

59 Global medical technology contacts
**Introduction**

The certainty of innovation

What a difference a year makes

There was much we were certain about when we released the inaugural edition of our medtech industry annual report a year ago, but we had no idea that – through a quirk of fate – the timing of the release would itself turn out to be significant. We are talking, of course, about the global financial crisis, which erupted in late September, just as *Pulse of the industry* was going to press. The crisis – since dubbed the “Great Recession” by many – has taken the global economy on a remarkable roller-coaster ride over the last twelve months. Stock markets vacillated in waves of volatility, credit ground to a halt before sputtering back, layoffs soared with only glimmers of a recovery.

There is a great deal that has differentiated this downturn. Analysts have variously described it as a massive reset, the end of “easy money,” a period of shifting gender roles, and the beginning of new power balances between East and West. While those are certainly valid characterizations, this period can equally be described as a time of endemic uncertainty. The crisis was born when credit markets seized up because lenders suddenly faced tremendous uncertainty about their own liquidity and access to capital. Companies, operating in an opaque business climate with heightened doubts about the solvency of counterparties and the strength of consumer demand, resorted to massive layoffs. And as US consumers faced new uncertainty about their job security and income stability, they reacted by reducing spending and propelling the savings rate to heights not seen in years.

Certainty in challenging times?

One certainty that this sector has relied on in crises past is that medtech – indeed, the entire healthcare segment – has always been a recession-proof industry. The question, of course, was whether that conventional wisdom would still hold amid the deepest recession in more than seven decades.

The industry’s financial performance, it is heartening to note, has largely held steady. The revenues of publicly traded medtech companies in the US and Europe grew 11% to US$289 billion. Organic growth during this period (net of acquisitions and foreign-exchange-rate fluctuations in both years) was no less impressive at roughly 5-6%. And while net income fell by 11% in 2008, this was mainly due to large one-time charges. After netting out these charges, the industry’s net income would have increased instead of falling. Still, the recession does appear to have taken a toll in the first half of 2009, when revenues remained essentially flat (a decline of less than 1%) compared to the same period in 2008.

The conventional wisdom appears to have held up – to a point. While medtech fared much better than most other industries at a time of widespread economic turmoil, it was not entirely immune to the effects of the crisis. The extraordinary depth and breadth of this recession have taken a severe toll on medtech’s customers and users, and it is not surprising that the industry’s financial performance has been dampened somewhat. As unemployment has skyrocketed, significant numbers of the US population have lost health insurance coverage. This, in turn, has led patients to postpone elective procedures and has raised levels of uncompensated care and bad debt at hospitals, which have responded in part by delaying purchases of capital equipment. Increased unemployment has also diminished tax revenues for many government-sponsored health programs. With their budgets under pressure, many private and public payors adopted aggressive cost-reduction measures, which have increased pricing pressures. The bottom line is that many medtech firms selling big-ticket and discretionary items have seen orders decline.

Any discussion of medtech financial performance, it should be remembered, is inevitably driven by the results of the largest companies. After all, the sector is dominated by a number of very large players, and the overall numbers mask the impact that the crisis has had on many small-cap and venture-backed firms. As of 31 December 2008, 25% of companies had less than a year of cash on hand – up from 20% a year earlier.

One area where the growing chasm between medtech’s haves and have-nots is most visible is in fundraising. US and European companies experienced a 38% drop in capital raised in 2008. However, these numbers were boosted considerably by a few outsized transactions conducted by two large European companies. Indeed, the decline in amount raised was even steeper in the US – where financing fell 53% – and Europe’s 73% increase in financing would actually have been a 44% decline in the absence of those two European companies. For medtech companies, as for companies in most industries, access to the public markets has become considerably more challenging. And while the amount of venture capital held up relatively well, Venture Capitalists (VCs) have become much more selective with their investments due to a lack of viable exits.

While larger, cash-flow-positive companies have not been impacted as severely by the turmoil in the capital markets, the crisis has raised the cost of capital for companies of all sizes. One consequence of this has been a considerable drop in Merger and Acquisition (M&A) activity. Deal-making has also been hurt by the retreat of Private Equity (PE) investors – whose
buying spree in recent years was fueled by the availability of cheap credit – and by valuation gaps between the expectations of sellers and the new realities of the market. The deals that did get done showed increasingly cautious buyers. Acquirers were only biting off what they could chew with regard to mature targets, and were attracted to later-stage, venture-backed companies that had taken some clinical, regulatory and reimbursement risk off the table.

More uncertainty ahead

Even as medtech companies deal with the fallout from a global recession that has increased uncertainty across the economy and affected the behavior of counterparties, a host of other changes looms on the horizon in the US, the world’s largest healthcare market. These changes – which are largely independent of the financial crisis – create new sources of uncertainty for companies and investors, including:

Product approval uncertainty

Medtech is a very diverse industry, and this diversity is reflected in the wide variety of products sold by the industry. Medtech products range from elastic bandages and bedpans to drug-eluting stents and MRI machines, and different products represent different levels of risk to patients. Reflecting these differences, the Food and Drug Administration (FDA) has had different approval processes for different types of products. Class II products – which pose a moderate level of risk to the user – do not require clinical trials. Instead, companies have been required to file a 510(k) submission demonstrating that a product is “substantially equivalent” to a predicate device (one that has been cleared by the FDA or marketed before 1976). The FDA is now considering restricting the types of products that can pursue a 510(k) clearance process, which would likely increase the time, cost and risk involved in getting FDA clearance for many products.

Reimbursement uncertainty

As policy-makers in the US and elsewhere wrestle with the competing challenges of expanding access to health insurance and reining in healthcare costs, it is likely they will turn to some form of comparative effectiveness – a system where reimbursement decisions are based not just on whether a product works but on the incremental benefit it delivers relative to its incremental cost. It is not yet clear what form comparative effectiveness might take in the US market, and it will

Medical technology at a glance – 2008

US$m, data for nonconglomerates except where indicated

<table>
<thead>
<tr>
<th>Public company data</th>
<th>Combined</th>
<th>Growth</th>
<th>US</th>
<th>US growth</th>
<th>Europe</th>
<th>Europe growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenues (total)</td>
<td>$289,392</td>
<td>11.0%</td>
<td>$188,779</td>
<td>9.1%</td>
<td>$100,613</td>
<td>14.8%</td>
</tr>
<tr>
<td>Nonconglomerates</td>
<td>$169,578</td>
<td>10.9%</td>
<td>$116,915</td>
<td>10.5%</td>
<td>$52,663</td>
<td>11.6%</td>
</tr>
<tr>
<td>Conglomerates</td>
<td>$119,814</td>
<td>11.2%</td>
<td>$71,864</td>
<td>6.8%</td>
<td>$47,950</td>
<td>18.4%</td>
</tr>
<tr>
<td>R&amp;D expense</td>
<td>$10,609</td>
<td>8.6%</td>
<td>$7,959</td>
<td>4.9%</td>
<td>$2,477</td>
<td>13.6%</td>
</tr>
<tr>
<td>Net income (loss)</td>
<td>$11,444</td>
<td>-11.3%</td>
<td>$6,479</td>
<td>-21.2%</td>
<td>$4,965</td>
<td>6.0%</td>
</tr>
<tr>
<td>Number of employees</td>
<td>663,870</td>
<td>1.6%</td>
<td>418,250</td>
<td>-0.5%</td>
<td>245,620</td>
<td>5.5%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of companies</th>
<th>Combined</th>
<th>Growth</th>
<th>US</th>
<th>US growth</th>
<th>Europe</th>
<th>Europe growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public companies</td>
<td>460</td>
<td>-3.8%</td>
<td>292</td>
<td>-5.8%</td>
<td>168</td>
<td>0%</td>
</tr>
<tr>
<td>VC-backed companies</td>
<td>1,247</td>
<td>n/a</td>
<td>677</td>
<td>n/a</td>
<td>570</td>
<td>-2.4%</td>
</tr>
</tbody>
</table>

Source: Ernst & Young. Growth is relative to 2007. Number of public companies includes conglomerate companies.
probably take years for such measures to be fully implemented. Still, any such move is likely to increase reimbursement risks for medtech companies, particularly since many medtech products were initially cleared for marketing without substantial clinical trials.

The Physician Payment Sunshine Act of 2009
Unlike drugs, which are developed at the bench, medtech product innovation often occurs at the bedside or the operating table in association with physicians. The Sunshine Act would require medical device manufacturers to report certain gifts and payments to physicians, with financial penalties for noncompliance. Critics of the proposed act fear that physicians will become cautious about working with medtech companies, slowing the pace of innovation and growth. While some larger companies have established internal training programs to enforce enterprise-wide ethical standards, they may struggle to gather all of the required data, and smaller firms may have insufficient resources for training and supporting such initiatives.

The certainty of innovation
The global economic crisis and the changes described above have significant implications for innovation and the medtech business model. This is a highly innovative industry, and its innovation has some unique characteristics. Medtech innovation typically occurs in rapid cycles, mostly in the form of small incremental improvements rather than major breakthroughs. Of course, the cumulative impact of numerous small-but-quick improvements adds up, both in improved outcomes and lower costs. As Stephen Ubl notes in his article, when the first implantable defibrillator was introduced, it cost US$80,000 and involved almost a month of hospital stay. Today, a comparable device has more functionality, costs half as much and requires only a few days in the hospital.

As one might expect, the funding, regulatory and deal-making environments have evolved in ways that support the unique nature of innovation in medtech. Processes for quicker regulatory approval and clearance, for instance, have enabled rapid innovation cycles. Venture capitalists have been attracted to the sector because these abbreviated pathways required relatively low amounts of funding and permitted quicker exits. Many small companies and their venture backers have focused on developing products that are specifically designed to fill the needs of larger companies. This has produced an active M&A environment, providing a steady stream of exits. Lastly, as mentioned above, much of the innovation in this sector occurs not at the bench but at the bedside. Close interactions with physicians provide the basis for iterative improvements using real-world data and feedback.

Now this model, which has successfully produced a steady stream of innovation, faces increased strain because of the convergence of several factors. The “new normal” in global financial markets means less capital for medtech going forward (because of massive deleveraging across the system rather than investor sentiment toward medtech per se). In addition, the higher cost of capital could mean less M&A activity in the months and years ahead. The assumptions supporting the medtech venture funding model are also changing. VCs are having to invest longer in the current market to carry their existing portfolio companies, and exits are less certain. Meanwhile, the added uncertainty around the regulatory process creates additional risk for companies and investors.

### The year in financing — 2008 (US$m)

<table>
<thead>
<tr>
<th>Type</th>
<th>Combined</th>
<th>Growth</th>
<th>US</th>
<th>US growth</th>
<th>Europe</th>
<th>Europe growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Venture financing</td>
<td>$4,339</td>
<td>-12.0%</td>
<td>$3,567</td>
<td>-10.2%</td>
<td>$772</td>
<td>-19.5%</td>
</tr>
<tr>
<td>IPO</td>
<td>$135</td>
<td>-92.6%</td>
<td>$115</td>
<td>-90.1%</td>
<td>$20</td>
<td>-97.1%</td>
</tr>
<tr>
<td>Follow-on public offering</td>
<td>$1,817</td>
<td>14.4%</td>
<td>$847</td>
<td>-44.9%</td>
<td>$970</td>
<td>6,079.6%</td>
</tr>
<tr>
<td>Convertible debt</td>
<td>$1,930</td>
<td>-66.8%</td>
<td>$1,111</td>
<td>-80.8%</td>
<td>$819</td>
<td>2,605.5%</td>
</tr>
<tr>
<td>PIPE</td>
<td>$1,002</td>
<td>67.3%</td>
<td>$360</td>
<td>-11.3%</td>
<td>$642</td>
<td>232.5%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>$9,222</strong></td>
<td><strong>-37.3%</strong></td>
<td><strong>$6,000</strong></td>
<td><strong>-53.3%</strong></td>
<td><strong>$3,222</strong></td>
<td><strong>72.8%</strong></td>
</tr>
</tbody>
</table>

Source: Ernst & Young. Growth is relative to 2007
But amid all this uncertainty, there is one certainty: innovation. As a society, we are certain to need medtech innovation, and innovation will certainly get done. Long-term trends, such as aging populations, large unmet medical needs and increasing prosperity in emerging markets, spell growing demand for healthcare and medtech products. And while healthcare reform and the accompanying need for greater efficiency will be challenging for many companies, these shifts also represent an opportunity. Just as information technology has generated huge advances in efficiency across the larger economy, the move to greater efficiency in the healthcare ecosystem will require tapping the power of innovative technologies to deliver healthcare. Diagnostics, for instance, will play a critical role in enhancing comparative effectiveness by identifying patients to whom certain treatments should be targeted, helping accelerate the shift to personalized medicine. And new generations of devices will provide much of the answer, for instance, through minimally invasive technologies that improve outcomes while lowering costs.

Navigating through uncertainty: four rules of the road

What should companies keep in mind as they operate in this challenging environment? In an industry as diverse as medtech, it’s hard to develop observations that cover companies in very different circumstances. Still, we think that most companies would be well served by keeping in mind four “rules of the road”:

1. Use capital efficiently
In a constrained funding environment, capital efficiency has become imperative for smaller companies looking to lower their burn rates and extend the life of their existing resources. But the principle also applies to larger firms, which face more stringent lenders, a higher overall cost of capital and an increasing need to focus on bottom-line in addition to top-line growth. More and more, doing more with less has become a universal theme.

2. Demonstrate value
Companies of all sizes need to track healthcare reform and understand how the changes being considered could affect their businesses. More important, though, they need to prepare for comparative effectiveness by identifying and articulating the value proposition for their products early in the development process. Some form of comparative effectiveness will undoubtedly be adopted, and companies would be wise to control as much of their destiny in demonstrating differentiated benefits as possible.

3. Address regulatory change
The medtech industry faces a host of proposed regulatory changes, from the ways in which products are granted marketing approval and clearance to restrictions on interactions with physicians. These changes could have profound impacts on everything from business plans to fundraising and commercialization strategies. Companies need to monitor these changes and adapt their strategies and operations accordingly.

4. Embrace business model innovation
Despite the significant challenges outlined above, the guest authors and roundtable participants in this year’s Pulse of the industry remain largely optimistic about the industry’s prospects. A major reason for their outlook is that medtech has survived numerous challenges and funding droughts in the past, largely thanks to the creativity and nimbleness of medtech firms. Now, to thrive in a changing regulatory and competitive environment, companies will need to apply that creativity to developing new business models, such as creative approaches to delivering healthcare outcomes rather than simply selling products. Innovation is a certainty. But it’s not just for products any more.

<table>
<thead>
<tr>
<th>Type</th>
<th>Combined</th>
<th>Growth</th>
<th>US</th>
<th>US growth</th>
<th>Europe</th>
<th>Europe growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total deals</td>
<td>113</td>
<td>-36.5%</td>
<td>79</td>
<td>-40.6%</td>
<td>58</td>
<td>-20.5%</td>
</tr>
<tr>
<td>Total deal dollars</td>
<td>$41,256</td>
<td>-33.4%</td>
<td>$29,311</td>
<td>-42.3%</td>
<td>$22,813</td>
<td>-18.6%</td>
</tr>
<tr>
<td>Average dollars per deal</td>
<td>$365</td>
<td>4.9%</td>
<td>$371</td>
<td>-2.9%</td>
<td>$393</td>
<td>2.4%</td>
</tr>
<tr>
<td>Deals of US$1+ billion</td>
<td>7</td>
<td>-53.3%</td>
<td>6</td>
<td>-50.0%</td>
<td>3</td>
<td>-50.0%</td>
</tr>
</tbody>
</table>

Source: Ernst & Young. Combined numbers between a US and European entity only count once in this column. Growth is relative to 2007.
As I write this article, the US Congress is considering a significant overhaul of the US healthcare system, and its outcome is as uncertain as a weather prediction. What is fairly certain, however, is that when 2009 draws to a close, some form of healthcare reform will have been enacted, and no segment of the healthcare system will remain unchanged – for better or worse.

What is the prognosis for medical technology in all of this? I am convinced that whatever shape health reform takes, the unique and essential role that medical technology plays in healthcare will become increasingly important.

Why do I believe this? First, we are living in the era of the life sciences: US life expectancy has grown to an all-time high of 78.1 years and the annual death rate has dropped to an all-time low of 760 deaths per 100,000 people; medical technology is rendering many previously debilitating or life-ending conditions a thing of the past; and diagnostic tests are not only discovering disease before a patient feels sick but can target the right treatment, for the right patient, at the right time. While this is impressive, we haven't seen anything yet. With a medical technology innovation life cycle of 18 months, better treatments are always just around the corner.

Second, improving the quality of care and achieving better patient outcomes are critical to successful reform, and all flow naturally from medical technology and diagnostics. Leading economists at United BioSource Corporation recently found that better prevention and quality of care in just 13 chronic and acute conditions could add US$1 trillion per year to US Gross Domestic Product (GDP) by 2023. These gains are from increased productivity when more people are healthy and able to contribute to the economy. The role of medical technology in helping people maintain productive, healthy lives is seen every day around the world, and it underscores the need for more – not less – innovation.

Increased efficiencies are also key, and here again medical technology plays an important role. Advancements in innovation are turning former inpatient procedures into outpatient procedures that dramatically reduce the length of hospital stays for many conditions. This results in reduced costs and better patient outcomes. In the early 1990s, for example, an Implantable Cardioverter-Defibrillator (ICD) cost approximately US$80,000 and required a patient to spend nearly a month in the hospital. By the early 2000s, the cost for an ICD was cut in half and hospital stays for the same procedure were one to three days.

Third, there are at most a handful of industries where the US can rightly claim to lead the world in ingenuity and also be a net exporter. Medical technology is one of them. The industry also contributes significantly to the US economy, providing jobs that pay on average 30% more than the average US job. Thanks to the “multiplier effect,” every medtech job also results in 4.5 additional jobs across the nation. And our industry is competitive. Medical device price changes have been consistently low, lagging behind both the Consumer Price Index and the Medical Services Price Index from 1989 to 2006.

For these and other reasons, I remain bullish about the future of medical technology. To be sure, AdvaMed and its members are not assuming that policy-makers are aware of the industry’s role in achieving gains to quality and efficiency. We have engaged fully in the health reform debate, even offering the industry’s own reform proposal in 2007, and have had seats at the table in both the Congress and the White House. We are focused on promoting the innovation ecosystem – from concept to design, from capital investment to regulatory approval – that has sustained US leadership in medical care and will play an essential role in capturing the efficiencies and improved quality of care that all of us want from healthcare reform.

I congratulate Ernst & Young for an excellent report that details a robust and vibrant industry with a very bright future.
European industry perspective

Innovation is the key for Europe's medtech industry

John Wilkinson
Eucomed
Chief Executive

A challenging environment

As we enter the latter part of 2009, there is room for both optimism and caution about the global financial crisis. There are some indications that, at a macroeconomic level, the worst is over. But it is certain that for individuals and many industries – our own included – significant challenges remain, and some are still on the way. Nevertheless, for the European medical technology industry, I anticipate that our record of being one of the least affected by the downturn will continue.

All will not be easy, however. Substantial increases in public debt resulting from the downturn will be with us for many years, and governments across Europe will be under enormous pressure to return public finances to sustainable levels. Most of the impact of this budget pressure has yet to be felt, although several countries, such as the Czech Republic, Poland, Slovakia and Hungary, are expected soon to introduce imminent and far-reaching cuts in healthcare reimbursement. For the more developed economies of Europe, budgetary measures are still to be outlined, and the future is clouded by forthcoming elections in the UK and Germany.

Innovation: the way forward

To protect and develop sustainable, high-quality healthcare in Europe – consistent with both citizens’ needs and their willingness to pay through taxation – we will need innovation. Using old procurement methods, restricting choice and buying old technologies at bargain prices might bring some temporary relief. But in the long run, the only sustainable solution is innovative new treatments that lower the total cost of care and simultaneously improve the patient experience.

There are some beacons of best practice in Europe – countries and health systems are pursuing technological solutions to their sustainability challenges. I hope that these lessons will be adopted by others that still view technology as purely a driver of cost. The clinicians, scientists and engineers that comprise the innovative leading edge of our industry, whether employed by companies or as part of public health systems and academia, can be further galvanized in support of the very real challenges and opportunities that lie ahead of us. For this to happen, everyone needs to embrace the need to innovate.

Europe has an enviable record of medical innovation that has helped spawn sectors such as heart rhythm management, orthopedic implants and modern ophthalmology. All of these had their origins in the minds of visionary clinicians and were translated into essential technologies by scientists and entrepreneurs who set up small, often poorly funded companies to bring the first generations of technology to market. Many of these companies became European subsidiaries of global medical technology companies, and investment continues as the companies grow and the technology is improved over successive innovation cycles. The current economic crisis, however, has dealt a hammer blow to those entrepreneurs seeking to found companies which could be the seeds of industry growth 10 and 15 years ahead. Venture funding has decreased considerably.

Outlook

Keeping the pipeline of innovation flowing is crucial to the future prosperity of Europe’s citizens. With the right measures, we can continue to provide the world with many of the technologies that will shape the future of healthcare delivery. These measures include improving innovation networks, increasing access to finance for emerging companies and, most important of all, encouraging the industry’s customers to recognize the key role that innovation can play in providing better services to patients at a lower total cost to the health system.
CEO roundtable

Change brings new opportunities

Medtech company leaders are grappling with a host of challenges these days. The global financial crisis has made financing scarce and financial exits challenging, as Initial Public Offerings (IPOs) have dried up and valuations have plummeted. Compounding these difficulties, executives face considerable uncertainty around proposed healthcare reform, as well as changes to the 510(k) clearance and reimbursement processes and the Physician Payment Sunshine Act.

To get some insight into these challenges, we caught up with four industry veterans who have extensive and varied experience in building and exiting companies on both sides of the Atlantic. Willy Michel is Chairman of Ypsomed, a publicly traded Swiss manufacturer of drug delivery systems. Rick Randall, CEO of US-based Trans1, successfully took the spine company public in 2007. Ron Sparks, CEO of Boston Scientific-spinout Navilyst Medical, sold his previous endeavor for US$1.3 billion to a PE investor. More recently, Dan Lemaitre sold CoreValve to Medtronic in April 2009 for US$700 million plus potential milestone-based earn-out payments.

The panel’s message is one of impending change — changes in financing models, technologies, business models, reimbursement, regulatory oversight and markets. But while change brings uncertainty, it also brings new opportunities.

Ernst & Young: How has the financial crisis impacted the medtech industry?

Randall: The unique confluence of the recession, the uncertainty around healthcare reform, and the paucity of financial exits — either IPOs or acquisitions — is having a serious impact on the medtech industry. I don't think I've seen as many companies close down and sell their assets as I'm seeing in this cycle. I've also heard of a couple of VCs that are closing their doors and I think we're going to see further VC firm contraction.

On the other hand, it's also a great time for large medtechs to consolidate and arm themselves with innovative technologies for the recovery. With valuations returning to more realistic levels, smart companies are going to buy some interesting VC-funded innovations and technologies at very reasonable prices.

Lemaitre: I agree with Rick. VCs and VC-backed companies are fighting for survival. We simply cannot sit and hope for a return of the IPO market. This is especially true for new, untested entities. As such, VCs and their emerging portfolio companies need to be in control of their destinies — how they spend their money, and how they manage their burn rate and infrastructure build. Investors want to see some ability to sustain long-term growth via top-line momentum. It’s about becoming cash flow positive, and if you can’t do that, then the question...
becomes, when do you start to court strategic partners who are looking for new technologies?

Sparks: To me, the lack of credit has had two major impacts. One, most privately held medtechs are unable to secure an exit through acquisition — many are going to wait for the financial crisis to end before they sell, because they’re worried about valuations. Two, customers are constrained. Hospitals are no longer able to access enough credit to buy capital equipment, especially big-ticket items. And the reduction in governments’ tax receipts has hampered their ability to buy products for their healthcare systems — which has had a pretty dramatic impact in Europe and Japan.

Ernst & Young: Which sector of the medical technology industry has the greatest opportunity for growth and investment?

Randall: While not sector specific, focusing on minimally invasive technologies for procedures where open surgery is currently the norm is a successful and time-tested strategy for growth. Minimally invasive procedures decrease morbidity rates, recuperation times and overall healthcare expenses. Another interesting opportunity is applying a technology early in a disease state to significantly impact downstream health and morbidity. For instance, by applying obesity treatment technologies early, patients can avoid diabetes, heart disease and a whole host of other co-morbidities associated with obesity.

Michel: Rick is correct. Products that deliver superior clinical results and contain costs will attract investors. Governments and private payors are placing increased importance on cost-effectiveness, and device manufacturers need to address these issues to succeed. One field that has great potential — regardless of disease area — is homecare devices. As healthcare systems strain to handle increased patient demands, there is a huge market opportunity for medical solutions that patients can safely and effectively control from the comfort of their own homes.

Ernst & Young: New requirements by the FDA and the Centers for Medicare and Medicaid (CMS) continue to increase the time and cost of obtaining product approval and reimbursement. How should medtech companies respond to these hurdles? How can companies better demonstrate the value proposition related to their products?

Lemaitre: In the US, we have a regulatory oversight process that has become so risk-averse that it fails to strike an appropriate balance between risk and benefit. We are operating in a litigious environment where there is so much trepidation about what can go wrong that we undervalue the medical benefits that products can deliver. Even the FDA has been placed in a position where it is afraid to be second-guessed on its decisions. The FDA will never be summoned by legislators and congratulated for approving a product. However, if one thing goes wrong with an approved product, you can be certain that FDA leaders will be quickly summoned and questioned about why they didn’t catch — or chose to ignore — particular side effects or risks.

Sparks: We need to reexamine the 510(k) process. More than 30 years after Section 510(k) of the Federal Food, Drug and Cosmetic Act was enacted, companies are still claiming that today’s great innovative products — which they want to price at premium levels — are essentially no different from products approved before 1976! I can’t say that we’re going to abolish the 510(k) process.

“...in the US, we have a regulatory oversight process that has become so risk-averse that it fails to strike an appropriate balance between risk and benefit. We are operating in a litigious environment where there is so much trepidation about what can go wrong that we undervalue the medical benefits that products can deliver.”
But there’s certainly going to be a shift, and I anticipate a higher level of scrutiny on some products, particularly those that are critical in nature.

Ernst & Young: Should medtech CEOs think about their corporate strategies differently today compared to two or three years ago?

Lemaître: Anybody who’s in this business for the long term would be smart to increase their exposure to self-pay because the alternative of having to rely on public reimbursement may not be that attractive in the future. So while it is very difficult to be a proponent for self-pay in the current economic cycle, having a self-pay market where people have already made the determination that they are willing to reach into their pockets to pay is a huge plus in the long term.

I also believe one of the most important questions an emerging company CEO should be asking themselves is, “are we in fact a company, or just a product line?” During the IPO cycle of 1996, we saw several product lines that were disguised as companies. Those product lines went public and we now know that model wasn’t practical. Depending on whether you’re a company or a product line, you’re going to have to spend money differently, build infrastructures differently and plan for an exit differently.

Sparks: With a few exceptions, the medtech industry outside the US is largely under-penetrated, even in some of the more mature markets. There is no question that a large driver of medtech for the foreseeable future will be the ex-US market. While most CEOs have had an ex-US strategy, they’d be foolish not to focus at least half of their efforts establishing their business abroad as quickly as they can.

Ernst & Young: Taking up Ron’s point, over the past several years, we’ve seen several companies execute ex-US strategies to position themselves for a successful M&A event. What would be your advice for medtech CEOs as they develop ex-US strategies?

Lemaître: Since Europe is a market that hasn’t been historically friendly to new technology or been very generous with reimbursement, when something does take off there first, it’s usually a pretty good harbinger of what could happen in the US. We obviously had a very successful Europe-first experience with CoreValve that resulted in an acquisition by Medtronic. However, to be fair, the CoreValve example may be the exception rather than the rule. In order to be successful in Europe, the product needs to be a novel, truly differentiated technology. We were successful with payors like the UK’s National Institute for Health and Clinical Excellence (NICE) because we were able to reduce the length of stay for patients, and ultimately reduce overall costs.

Randall: I wholeheartedly agree with Dan. I think we will continue to see an increase in both Premarket approval (PMA) submissions and FDA approvals for devices with data solely derived from Europe, but I also believe an ex-US strategy first is not for everyone. As Dan will tell you, one size does not fit all. For example, the price points you can achieve for spine and orthopedic products are significantly lower in European markets than they are in the US. While a value proposition of very good clinical results and proper financial incentives for the payor, provider and physician will be important in the world of healthcare reform in the US – I would argue that ex-US markets may not be the place to prove those points.

Michel: I think it is also important for US-based manufacturers to note that Europe is a very different market than the US. Not only do European healthcare systems expect new devices to deliver greater innovation and cost savings, but each one of the continent’s countries has its own distinct patient markets and special regulations. In short, one size does not fit all in Europe.

“Products that deliver superior clinical results and contain costs will attract investors. Governments and private payors are placing increased importance on cost-effectiveness and device manufacturers need to address these issues to succeed.”

10 Pulse of the industry  Medical technology report 2009
Ernst & Young: The success of the medical technology sector has been built on physician-driven innovation. What will be the impact of recent settlements of the US Department of Justice (DOJ) with certain medtech companies, and of the Physician Payment Sunshine Act, on the industry’s ability to collaboratively develop new technologies with physicians?

Lemaitre: It’s important to remember that medical device innovation – unlike innovation in the drug industry – does not start at the bench. It starts at the bedside. At CoreValve, for example, we had no idea about the full capabilities of our valve technology until it got out into the hands of physicians who taught us how to use our product better. The tragedy of these government investigations is that some people are driving a wedge between physicians and companies by portraying their relationships as dirty or conflicted. Physicians are becoming more leery about having close company relationships, and, unfortunately, the people overseeing the regulatory process don’t understand that their actions may slow down the pace of technology innovation, training and the overall growth of the industry.

Sparks: Keep in mind that what the DOJ was targeting in my view was “if you pay me, I’ll buy your stuff” arrangements. I have no doubt this was occurring. The DOJ has taken away the ability, particularly for smaller companies, to buy market share through such relationships and million-dollar consulting fees. That being said, to demonize the doctor/industry relationship is ridiculous. Contrary to what the general public thinks, a surgeon or physician does not get trained on implanting a new coronary stent in medical school; that happens through relationships with company sales representatives. If spending with physicians was eliminated, training and education would come to a screeching halt. There is no money out there for product training. Hospitals don’t have it, and colleges and universities don’t have it. They don’t even have the ability to do it.

Randall: Like Ron, I actually view these inquiries as a positive. Most of the DOJ’s concerns were focused on physicians who were being paid for product utilization in the guise of consulting arrangements. Going forward, I don’t think physician-driven innovation is going to stop. However, physicians’ utilization will more clearly be based on the merits of a particular product and not based upon who’s paying them the most. I don’t think these past practices benefitted the patient or product innovation very well.

“We need to reexamine the 510(k) process. More than thirty years after Section 510(k) of the Federal Food, Drug and Cosmetic Act was enacted, companies are still claiming that today’s great innovative products – that they want to price at premium levels – are essentially no different from products approved before 1976!”

Ernst & Young: How do you think healthcare reform will impact the medical technology industry?

Michel: In areas like diabetes and oncology, where it is unfeasible to deny or reduce care for patients in need of critical treatments, I don’t expect any serious short- or long-term impact. However, where healthcare reform is likely to make its mark is in other sectors like orthopedic or cardiovascular.

Randall: At TranS1, we are already experiencing some of the short-term pressures of healthcare reform. Hospitals are driving down the costs of less differentiated, commodity-type products and they’ve shortened the list of physician-preferred items. The current media storm around healthcare reform is also further empowering hospital administrators to enforce these cost-cutting policies, especially as physicians focus more on preserving their personal income. In the long term, there’s no doubt in my mind that the industry will need to produce more cost-effective therapies with compelling clinical outcomes.

Sparks: I don’t see any of the proposed reforms as earth-shattering. We’ve been up against such reforms in other markets outside the United States for many years and we continue to operate there without any disastrous consequences. I do think the one wild card in this equation is utilization. Unfortunately, the only way to control healthcare costs is by controlling utilization. While controlling utilization is not necessarily good news for the medtech industry, it’s probably inevitable. In the short term, more people being able to get healthcare is a great thing – there’s no debate. Who pays for it is the debate.
Leading indicators
What a difference a year makes

31 December 2007 to 31 December 2008

- European public medtech market cap DOWN 34%
- S&P 500 DOWN 38%
- Medtech total financing DOWN 38%
- Medtech transaction dollars DOWN 33%
- Public medtech Revenues UP 11%
- US public medtech market cap DOWN 38%
- Public medtech net income DOWN 11%
- DJ Euro STOXX 50 DOWN 34%

30 June 2008 to 30 June 2009

- US public debt UP 22%
- US business bankruptcy filings UP 53%
- EU 27 government debt UP 5%
- US median home price DOWN 14%
- Medtech transaction dollars DOWN 70%
- US public medtech market cap DOWN 24%
- Medtech total financing DOWN 43%
- US unemployment UP 5.6%–9.5%
- US unemployment-up 6.8%–8.8%
- European unemployment UP 6.8%–8.8%
- Public medtech Revenues UP 11%
US market capitalization

Source: Ernst & Young, Capital IQ

European market capitalization

Source: Ernst & Young, Capital IQ
US hospital perspective

US hospitals under pressure

While healthcare is typically seen as a recession-proof sector, the global economic downturn and crisis in the credit markets has significantly reduced funds available to many hospitals that use credit or investment income to fund operations and capital expenditures. The distress is likely to continue in the near term as interest rates for variable bonds rise and credit tightens further.

According to an Urban Institute study, for each 1% increase in the US unemployment rate, 2.5 million beneficiaries and their dependents will lose employer-sponsored health insurance coverage. As unemployment has ratcheted up in this recession, the newly unemployed, underinsured and uninsured individuals are adding to the demands on safety-net programs such as Medicaid and the State Children’s Health Insurance Program (SCHIP) at a time when the state tax revenues used to fund these programs are in serious decline. The likely response by healthcare providers will be to increase controls over bad debts (e.g., uncompensated care) and expenditures.

Academic medical centers and public hospitals, for instance, feel the crunch particularly acutely, as they treat a higher number of uninsured and government-sponsored (e.g., Medicare, Medicaid, SCHIP) patients and a lower volume of commercial patients (those with non-government-sponsored health plans). Profits from commercial patients are typically insufficient to cover losses incurred on the uninsured or government-sponsored patients, weakening these hospitals’ ability to invest in building infrastructure, capital equipment and technology.

How will hospitals manage cash flow?
Healthcare providers are reviewing and prioritizing all significant expenditures for facility improvements, capital equipment and technology. An April 2009 American Hospital Association (AHA) survey reports that 8 of 10 hospitals have cut capital spending for facility upgrades, clinical or information technology. Facility improvements will be eliminated or delayed unless costs can be offset quickly by enhanced revenues from incremental services.

While healthcare providers and consumers agree that Electronic Health Records (EHRs) are vital to the improvement of quality and outcomes for patients, a 300- to 500-bed hospital can expect to spend US$20 million to implement EHR technology. Based on provisions in the current stimulus package to promote EHRs, such a hospital might receive US$8 million to US$12 million from the government – viewed by many as a sound deal. However, with shrinking funds for capital expenditures, reduced endowments and limited financing capacity, there are real questions about where the remaining capital will come from.

In addition to prioritizing and reducing capital expenditures, healthcare providers have taken other actions, including workforce reductions, changes to benefit plans, reductions in conference spending for employees, delayed purchases of new or replacement technology and reductions of services to the community.

As a result of these pressures, many medtechs have begun to proactively change the way they operate. In one response, General Electric announced in May 2009 its intention to shift 50% (US$500 million) of its Research and Development (R&D) and commercialization strategy from high-end technologies to lower-cost products that have mass appeal in emerging markets and rural areas. This announcement came after the company revealed a 2009 first-quarter drop in profits of more than 20% and a 9% dip in revenue. According to CEO Jeff Immelt, “The high end in healthcare is never going away, but this will make us broader in terms of price points and offerings.”

Left to their own devices
With capital expenditures in decline across the industry, hospital negotiating positions for high-cost equipment, technology and devices may improve as medical device and technology companies work to maintain market share and profits. Hospitals can be expected to exert more pressure in negotiations for price concessions and will seek to limit the number of approved devices for a particular procedure to concentrate buying power, at the expense of physician choice. Medical supply and device companies, underperforming against projections, may refocus sales efforts and contracting to include discounts or rebates for advanced purchases.
Venture capital perspective

Venture capitalists speak out

Over the past several years, roughly one out of every three dollars invested by venture capitalists has gone into healthcare. Of that healthcare pool, roughly one out of every three dollars has gone into medical technology. Given the impact of the current financial crisis, and the impending reforms to the world’s healthcare systems, we asked a handful of venture capitalists how their future views of medical technology investment have changed.

“The current cloud of uncertainty hanging over healthcare has had a chilling effect on medtech investments in 2009. As changes that adversely affect the medtech industry are pushed by the White House, FDA and CMS, venture dollars for innovation will be managed differently in the future. Many venture firms will avoid the most revolutionary technologies as the risk/reward paradigm has become imbalanced. Unless appropriate incentives are maintained for entrepreneurs and investors, current technologies may only receive incremental improvements. Medtech can survive and thrive with appropriate reforms, but government involvement must be limited.”

— John Deedrick, Accuitive Medical Ventures

“The pressure to contain costs and obtain reimbursements for new medical devices has never been harder. With a slew of issues to contend with, including the recession, the lack of an IPO market, patent reform, the Physician Sunshine Act, comparative effectiveness – and of course, healthcare reform – there are plenty of reasons to be negative about medtech right now. However, looking back at other downturns, this may be one of the best times to invest in medtech. Should coverage be extended to all Americans, the result will be expanded markets and greater utilization of medtech products. As prices and the competition for deals have come down in this past cycle, it may be a great time for investors to place more money into the sector.”

— Mark Wan, Three Arch Partners

“Despite the global financial crisis and worldwide healthcare challenges, medical technology is and will remain an attractive area of investment for venture capitalists. As the effects of the impending healthcare reforms are felt, the focus will shift to technologies that are targeted towards decreasing medical costs, especially those incurred within the hospital. Other technologies that will attract the attention of the investment community are ones that dramatically decrease the risks of currently complex medical procedures and improve health outcomes. The business models that will be most attractive to investors will be capital-efficient companies with market-ready product platforms.”

— Zev Scherl, NewSpring Capital

“In the past, emerging life science companies and the healthcare venture industry only had to worry that their new products were both safe and efficacious. Today, this paradigm has shifted. In the future, successful medtech companies (and their investors) will need to show not only that their products are safe and efficacious, but that they also improve outcomes and are cost effective. While the time and capital required to develop new products is likely to increase, those companies that demonstrate improved outcomes at a lower cost will be well positioned for success in the new model of modern healthcare.”

— Evan Melrose, PTV Sciences

“Given the current economic environment, there aren't too many segments that are as attractive to venture capital investment as medical technology. Unlike other cyclical industries, medtech has historically generated above-average levels of profitability. Population growth, aging demographics and broader access to healthcare, especially in the US and the developing world, will have a positive effect on overall health spending and medtech investment. While pricing and reimbursement pressures will be a challenge, they also present the industry with a great opportunity – an opportunity to produce innovative technologies that reduce the cost of healthcare while saving and improving lives.”

— Daniel Kusio, BVgroup
Breakdown of companies

As of 1 January 2009, there were 1,707 medical technology companies (for the definition of a medical technology company, please go to page 55) being tracked by this publication. Of these, 460 (27% of the total companies) were publicly traded – down 4% from 478 a year earlier. The United States experienced a 6% total drop in public medtech companies from 310 to 292, while Europe remained flat at 168. This list of 460 companies largely consisted of pure-play medtechs, but also included 23 conglomerates (14 in the US, 9 in Europe) that derived a significant amount of their total revenue from medtech products. In addition to the public companies, there were also 1,247 VC-backed companies; 677 (54% of all VC-backed companies) were based in the US and 570 (46%) were headquartered in Europe.

Product type

By far, the largest concentration of companies by product type was in "therapeutic devices," which accounted for 52% of all companies. Exactly 50% of all publicly traded medtech companies and 53% of all VC-backed companies were selling or developing therapeutic devices. In the US, 58% of all medtechs were therapeutic device companies, while that figure fell to 46% in Europe. Among the subsegments of therapeutic devices, cardiovascular/vascular was the largest with 190 companies (141 in the US; 49 in Europe), followed by orthopedic with 145 companies (79 in the US; 66 in Europe). Overall, nonimaging diagnostics (387 companies), imaging (186), research and other equipment (175) and other (56) rounded out the remaining 48% of product types.
Geography

The geographic distribution of the medtech industry is similarly concentrated. Of the 969 public (including conglomerates) and venture-backed medtechs in the US, 52% were headquartered in one of three states – California, Massachusetts and Minnesota. Within these states, several metropolitan areas stand out for having created flourishing and sustainable medtech clusters, most notably the San Francisco Bay Area, Orange County in California, San Diego, Boston and Minneapolis. Similar to the geographic concentration within the US, 56% of the 738 public and venture backed European medtechs were headquartered in just three countries: the UK, Israel and Germany. Adding France and Sweden, these five countries accounted for 77% of all European companies. Whether located in the US or Europe, thriving clusters tend to have several factors that are critical to their success. These include a population of skilled workers (scientific and managerial), access to financing (strong venture and banking communities) and a robust network of supportive institutions (hospitals, universities, service and supplier companies and local governments).
The revenues of US and European publicly traded medical technology companies grew 11.0% last year, from US$260.7 billion in 2007 to US$289.4 billion in 2008. US public medtechs accounted for nearly two-thirds of the combined revenues in 2008, including 69% of the total nonconglomerate revenues and 60% of conglomerate revenues. Overall, revenue growth for US and European nonconglomerates was up 10.9%, while conglomerates’ was up 11.2%. While organic expansion and acquisitions helped fuel these increases, foreign-exchange tailwinds helped drive much of this revenue growth in the United States. On the flip side, foreign-exchange fluctuations had a mixed impact on European revenues.

While conglomerates report revenue for their medtech divisions, they do not typically report other financial results, such as R&D expenditures or net income. Therefore, in order to provide a comprehensive analysis of financial results, the remainder of this section will focus primarily on the nonconglomerate companies.

R&D expense, a critical barometer of future financial success, experienced an 8.6% bump in 2008. Net income decreased by 11.3% in 2008 to US$11.4 billion. This deterioration in net income was driven mostly by the US (where net income fell 21.2%) and was primarily the result of US$2.8 billion of goodwill and intangible asset impairment charges and other assorted charges at Boston Scientific. However, absent these expenses – primarily related to Boston Scientific’s 2006 acquisition of Guidant Corporation – global net income would have increased.
Cash and short-term investments also dropped 8.4% among US and European medtechs, with the US down 11.3% and Europe off only 3.1%. While liquidity has been an issue for some small- and mid-cap companies, overall cash balances in the US were down mostly due to acquisitions financed with cash, most notably by Medtronic, Inverness Medical Innovations and Zimmer.

As a result of acquisitions of US-based companies, European nonconglomerates actually increased employment 5.8%, adding nearly 13,000 new jobs (for a total of 245,620). The continent as a whole kept its number of public companies flat at 168. This increase in payroll numbers was largely the result of a string of acquisitions of US-based companies by European medtechs (Philips, Fresenius Kabi, Roche and Getinge). Across the pond, US medtech company payrolls remained essentially unchanged (down 0.5% to 418,250), while the number of companies fell by 17 (5.8%) as a result of acquisitions and closures. Overall, the full impact of the financial crisis and the recession had yet to reach industry payrolls by the end of 2008. As 2009 has progressed, announced layoffs and restructurings have become increasingly common within the industry.

Although medtech stocks have traditionally been a defensive play for investors in difficult economic times, the pressures of the recession and the uncertainty of proposed healthcare reform in the United States were a drag on the industry in 2008. Public valuations of medtech companies were pounded on both sides of the Atlantic as aggregate market capitalizations of US and European companies were each off by 38%. While mid-cap medtechs (those with market caps of US$1–5 billion) did outperform the broader markets in 2008, public medtechs as a whole did no better than the Dow Industrial, NASDAQ or European indices. Not surprisingly, small and micro caps significantly underperformed the industry and the broader markets.

There is no question that the events of 2008 and the first half of 2009 have created a host of challenges for US and European medical technology companies. The global recession has affected the way medtech companies conduct business — especially emerging R&D-stage companies that lacked access to capital. While corporate balance sheets remained relatively strong for most of the larger medtechs, the lack of access to capital and declining stock prices made it more difficult for emerging companies to finance their operations and for midsize medtechs to complete acquisitions.

Providers under pressure

While the US and European healthcare provider segments are very different — in terms of business models, private versus public ownership and for-profit
orientation – both segments were significantly affected by the global financial crisis. With their sources of income under pressure, providers and government health systems began to focus on operational efficiency and cost-containment efforts. US hospitals and healthcare providers were hit particularly hard by a perfect storm of heightened challenges. As more and more cost-sensitive consumers delayed elective and out-of-pocket procedures, providers encountered declines in admissions. At the same time, as unemployment as a percent of the US population approached double digits, hospitals had to provide more uncompensated care to uninsured patients. These factors have coincided with a period in which government-run programs such as Medicare and Medicaid – payments for which constitute about half of hospital revenues – were tightening reimbursement rates paid to hospitals. To make matters worse, many hospitals had relied excessively on cheap and easily accessible capital, investment income and charitable donations to strengthen their balance sheets and to fund capital expenditures. With each of these sources of funding constrained, hospitals became more cautious about their own financial health and began reining in many expenditures.

In an April 2009 survey of its members, the American Hospital Association (AHA) found that 90% of hospitals had made cutbacks, with nearly 50% of them reducing staff and 80% cutting administrative expenses. According to many other sources, capital expenditures are expected to drop anywhere between 20% and 50% in 2009, as hospitals either keep equipment for longer or delay replacing equipment until absolutely necessary. This situation has implications for medtech companies in fields like imaging, robotic surgical systems and other hospital equipment/furniture – these segments anticipate lower growth rates or even decreases in revenue in 2009 and 2010.

In 2008, the revenues of nonconglomerates grew an impressive 10.5% relative to 2007, which far exceeded the growth rates achieved in recent years despite the global recession. While organic growth and a decline in the number of public company take-outs certainly helped to drive this double-digit expansion, favorable foreign-exchange rates were also a key driver. In fact, in the absence of currency fluctuations, revenue growth at the 10 largest US nonconglomerate medtechs would have been 5.7% instead of 8.7%. However, as the economic downturn took hold in the fourth quarter of 2008, the US dollar strengthened considerably. Almost overnight, many of the same US companies that had benefitted from their overseas sales earlier in the year began to experience significant headwinds due to the relative weakness of foreign currencies compared to the US dollar. According to Deutsche Bank, foreign exchange headwinds hurt medtechs’ fourth-quarter sales by 3.3% – but while the dollar remained relatively strong through the beginning of 2009, it has become increasingly weak versus the euro as the year has progressed. Consequently,

**US financial performance**

**US revenues**

US publicly traded medical technology companies earned revenues of US$188.8 billion in 2008 – a 9.1% increase over the US$173 billion reported in 2007. This comes on the heels of a 1.4% decrease between 2006 and 2007. Of this total, 62% (US$116.9 billion) was derived from nonconglomerate organizations, and 38% (US$71.9 billion) came from conglomerates. The medtech divisions of these conglomerates saw a healthy 6.8% revenue growth rate in 2008. In fact, each of the 14 conglomerates grew revenues in 2008, and four of them – Cardinal Health (which spun off as CareFusion in February 2009), Teleflex Medical, Abbott and Genzyme – achieved year-over-year growth rates of at least 20%.

In 2008, the revenues of nonconglomerates grew an impressive 10.5% relative to 2007, which far exceeded the growth rates achieved in recent years despite the global recession. While organic growth and a decline in the number of public company take-outs certainly helped to drive this double-digit expansion, favorable foreign-exchange rates were also a key driver. In fact, in the absence of currency fluctuations, revenue growth at the 10 largest US nonconglomerate medtechs would have been 5.7% instead of 8.7%. However, as the economic downturn took hold in the fourth quarter of 2008, the US dollar strengthened considerably. Almost overnight, many of the same US companies that had benefitted from their overseas sales earlier in the year began to experience significant headwinds due to the relative weakness of foreign currencies compared to the US dollar. According to Deutsche Bank, foreign exchange headwinds hurt medtechs’ fourth-quarter sales by 3.3% – but while the dollar remained relatively strong through the beginning of 2009, it has become increasingly weak versus the euro as the year has progressed. Consequently,
earnings of US-based medtechs have suffered through the first six months of 2009, placing additional pressure on companies to drive revenue growth in an already difficult economic environment.

A number of product groups and segments experienced very healthy increases on their top lines. Nonimaging diagnostics saw the biggest percentage revenue increase (22% or US$2.2 billion) to US$12.3 billion in 2008. This growth was largely fueled by a combination of recent acquisitions and organic growth at Inverness Medical Innovation (up US$832 million or 99%), and by Becton, Dickinson and company (up US$796 million or 13%), which, as we discussed above, derived nearly 50% of its growth from a favorable foreign exchange conversion. Research and other equipment, imaging and therapeutic devices all registered aggregate growth rates of at least 9% in 2008.

Within the therapeutic devices segment, women’s health revenues skyrocketed 114% (up US$985 million) solely on the back of Hologic. Hologic increased its revenues by 127% in 2008 (up US$936 million) due to the 2007 Cytyc acquisition. Under Ernst & Young’s classification, Cytyc had been listed as a nonimaging diagnostics company. If Cytyc’s 2007 revenue was reclassified, the women’s health segment’s year-over-year increase still would have been a healthy 25.6%. NxStage Medical (up 115% or US$69 million) and Insulet (up 170% or US$23 million) led the 33% increase in hematology/renal, while Varian Medical and Accuray helped drive a 17% growth rate in oncology. Of the top five fastest-growing areas in therapeutic devices, it is important to note that none of these segments lost a single company to acquisition.

Reflecting the negative pressures from the recession and a strengthening dollar, US medtech revenues were down during the first half of 2009 versus the same period in 2008 – albeit by a modest 0.8%. Led by the hematology/renal, multiple and oncology therapeutic devices segments, nonconglomerate medtech revenues actually grew 1.4% in the first half of 2009. These three segments – with Medtronic and Covidien driving growth in the “multiple” segment – produced organic growth due to the non-elective nature of their product lines. Conversely, segments such as aesthetics and dental that sell products that are elective in nature and involve a high degree of self-pay saw their revenues tumble in the first half of 2009 due to a recession-led drop in demand. Conglomerates as a whole were down 4.4%, with only three companies, Abbott (up 10.6%), Genzyme (up 8.8%) and Kimberly-Clark (up 4.8%), posting year-over-year gains. Aesthetics-focused Allergan (down 15.6%) and imaging giant GE Healthcare (down 10.4%) suffered the largest revenue drops by conglomerates thus far in 2009.

Other US financial indicators
While medtech’s top line grew at a healthy clip in 2008, the bottom line took quite a hit as aggregate net income was down 21% to US$6.5 billion. However, this was driven primarily by special charges at a few large companies, in the absence of which net income would have been up by about 29%. Examples of large charges include Boston Scientific’s US$2.8 billion write-down of goodwill and intangible assets primarily related to the Guidant acquisition. Other big drivers of the aggregate decline in earnings included Medtronic, which dropped 20% (US$571 million) to US$2.2 billion as a result of after-tax special, restructuring, in-process R&D and litigation charges of US$742 million, and Hologic’s US$565 million of in-process R&D charges in connection with the Cytyc and Third Wave Technologies acquisitions. Conversely, companies like Covidien (US$1.7 billion, up 498%), Illumina (US$329 million, up 118%) and Thermo Fisher Scientific (US$233, up 31%) all drove substantial increases in their bottom lines. The Illumina increase was in part due to a significant in-process R&D charge in 2007, whereas the Covidien increase was due in large part to a US$1.2 billion class-action settlement allocated by its prior parent, Tyco International.
Percentage declines in US market capitalization — 31 December 2007 to 31 December 2008
The impact on valuations differed across segments

| Therapeutic devices (TD) - cardiovascular/vascular | TD - neurology |
| Nonimaging diagnostics | TD - respiratory |
| TD - multiple | Research and other equipment |
| Other | Imaging |
| TD - urology/pelvic | TD - oncology |
| TD - hematology/renal | TD - orthopedic |
| TD - dental | TD - non-disease-specific |
| TD - ophthalmic | TD - women's health |
| TD - aesthetics | TD - wound care |

Market caps for several segments nearly returned to year-end 2007 levels

Source: Ernst & Young
Through the first six months of 2009, net income was down US$2.9 billion, or 51.8%. However, the majority of this was attributable to write-downs for the impairment of goodwill and other intangibles by Hologic (US$2.3 billion, primarily related to Cytyc acquisition) and Hill-Rom (US$466 million, primarily related to goodwill impairment.)

Cash and short-term investments were down by 10.6% in 2008, with roughly 60% of medtechs seeing their cash and investment positions fall in 2008. The number of medtechs with less than one year of cash also jumped from 24% in 2007 to 30% in 2008. The downward trend in overall cash balances continued through the first six months of 2009 when 63% of companies ended with less cash and short-term investments than the same period the year before.

While cash and liquidity were a concern for some companies, R&D expenses inched up 4.9% to US$8.0 billion in 2008 – its highest level in at least five years.

US medtech stocks remained fairly steady through the first nine months of 2008. As of 30 September, the industry’s aggregate market capitalization (excluding conglomerates) far outpaced the broader markets and was down only 0.4% relative to the beginning of the year. However, in the fourth quarter, US medtech stocks followed the overall market and plummeted sharply. By the end of 2008, the industry’s market cap was down 37.7%, essentially performing no better than the Dow Jones Industrial Average or the S&P 500. While no group within the industry was left unscathed (all segments had lost about one-fourth or more of their value), certain segments were hit harder than others. In

### Going, going, gone?

**Recent US public company bankruptcies, reorganizations and other actions**

<table>
<thead>
<tr>
<th>Company</th>
<th>Product type (disease)</th>
<th>Company action</th>
<th>Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>ARTES Medical</td>
<td>Therapeutic devices (aesthetics)</td>
<td>Chapter 7 bankruptcy</td>
<td>December 2008</td>
</tr>
<tr>
<td>Northstar Neuroscience</td>
<td>Therapeutic devices (neurology)</td>
<td>Liquidation and dissolution</td>
<td>January 2009</td>
</tr>
<tr>
<td>CHAD Therapeutics</td>
<td>Therapeutic devices (respiratory)</td>
<td>Chapter 7 bankruptcy</td>
<td>January 2009</td>
</tr>
<tr>
<td>Arbios Systems</td>
<td>Therapeutic devices (hematology/renal)</td>
<td>Chapter 11 reorganization</td>
<td>January 2009</td>
</tr>
<tr>
<td>North American Scientific</td>
<td>Therapeutic devices (oncology)</td>
<td>Chapter 11 reorganization</td>
<td>March 2009</td>
</tr>
<tr>
<td>Vermillion</td>
<td>Nonimaging diagnostics</td>
<td>Chapter 11 reorganization</td>
<td>April 2009</td>
</tr>
<tr>
<td>Nanogen</td>
<td>Nonimaging diagnostics</td>
<td>Chapter 11 reorganization (sold assets to The Elitech Group in July 2009)</td>
<td>May 2009</td>
</tr>
<tr>
<td>XTENT</td>
<td>Therapeutic devices (cardiovascular/vascular)</td>
<td>Liquidation and dissolution</td>
<td>May 2009</td>
</tr>
</tbody>
</table>
particular, aesthetics — due to the expected decrease of discretionary spending on elective procedures — and imaging — due to the expected sharp downturn in hospital capital expenditures — each took larger-than-average hits to their valuations. However, as fears of a prolonged recession began to subside and the outlook for future economic growth improved, both the broader markets and medtech stocks in particular saw a rally through the first half of the year. US medtech stocks were up 11% overall, and several segments nearly returned to their year-end 2007 levels: cardiovascular/vascular (flat), multiple (-3%), orthopedic (-4%) and research and other equipment (-5%).

European financial performance

European revenues

European publicly held medical technology companies’ revenues grew 6.9% in 2008, to €68.4 billion (US$100.6 billion). The 2008 revenue increase is particularly impressive when one considers the negative impact of foreign exchange rate fluctuations. While a handful of companies such as Alcon, Fresenius and Smith & Nephew actually benefitted from currency fluctuations, a strong euro throughout most of 2008 (and weaker US dollar and Japanese yen) impacted the top lines for the majority of European companies. Unlike their US counterparts, European companies faced a steady foreign exchange headwind that was responsible for shaving between 1% and 5% of total revenue.

Overall, nonconglomerates drove 52% (€35.8 billion; US$52.7 billion) of the total revenue increase, while the remaining 48% (€34.4 billion; US$48.0 billion) was earned by the medtech divisions of nine conglomerates. Unlike in the US, where nonconglomerates drove
the majority of revenue growth in 2008, in Europe, conglomerates (up 10.3%) were responsible for much of the revenue increase. With Siemens and Philips leading the charge, seven of the nine European conglomerates experienced revenue growth. Both Siemens’ and Philips’ revenue growth was principally fueled by recent acquisitions: Siemens was up 13.4% (£1.2 billion; US$1.8 billion) due in part to the 2007 purchase of Dade Behring, while Philips was up 15.2% (£1.0 billion; US$1.5 billion), thanks in part to the contributions of Respironics, also acquired in 2007.

Driven by a combination of organic and acquisition-based growth posted by Sweden’s Getinge AB and Germany’s MeVis Medical Solutions, the imaging segment led nonconglomerates in revenue growth (11%), which was closely followed by a 9% growth in research and other equipment. Similarly to the US, all four primary product groups experienced revenue growth between 2007 and 2008. Of the therapeutic devices segments – which constituted nearly 50% of European revenue in 2008 – oncology (up 41%) and non-disease-specific (up 14%) were two of the biggest revenue gainers in percentage terms. Oncology’s growth was driven by the organic growth of Belgium-based Ion Beam Applications (up 56%), a maker of cyclotrons and radiopharmaceutical markers, as well as by Germany’s Eckert & Ziegler (up 62%), an isotope technology specialist. Revenue of Spanish diagnostic and medical materials company Grifols led the growth in the non-disease-specific segment. Grifols’ 15.8% growth (£111 million; US$163 million) was the result of organic growth in all three of its operating divisions.

Getinge AB of Sweden, a leading manufacturer of surgical, infection control and wound care products, delivered Europe’s largest overall revenue growth in 2008 – up 17.2% or SEK 2.8 billion (£258 million; US$364 million). While the company did enjoy healthy organic growth, a key reason for its performance was the inclusion of the cardiac and vascular surgery divisions it had purchased for US$750 million from Boston Scientific in late 2007. French ophthalmic company, Essilor International, also used acquisitions and geographic expansions to fuel a revenue increase of €166 million (US$244 million) in 2008.

Other European financial indicators
While the aggregate net income of the US sector tumbled by more than 20% in 2008, net income of European companies dropped only 1.3% during the same period. Fifty-five percent of nonconglomerates, including the top three income producers in Europe – Alcon (up 20.2% to €821 million; US$1.2 billion), Fresenius Medical (up 6.2% to €556 million; US$818 million) and Synthes (up 11.8% to €500 million; US$735 million) – delivered impressive net income growth in 2008. Alcon, a Swiss maker of ophthalmic products, contributed more than 24% of Europe’s nonconglomerate net income. In July 2008, Alcon had 25% of its equity stake transferred from its parent Nestle SA to Novartis AG in a SFr11.1 billion (US$10.5 billion) deal. (For more details, refer to the transactions section of this report.) On the flip side, dental companies such as Straumann Holding and Nobel Biocare, aesthetic implant manufacturer Q-Med and diagnostic test-kit maker Trinity Biotech all experienced notable year-over-year declines in net income. Causes for these losses ranged from revaluations of

<table>
<thead>
<tr>
<th>Top European revenue growth leaders in 2008</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Company</strong></td>
</tr>
<tr>
<td>Getinge</td>
</tr>
<tr>
<td>Essilor International</td>
</tr>
<tr>
<td>Synthes</td>
</tr>
<tr>
<td>Qiagen</td>
</tr>
<tr>
<td>Smith &amp; Nephew</td>
</tr>
</tbody>
</table>

Source: Ernst & Young
intangible assets and noncash write-downs
to restructuring and impairment charges.
Most of these companies produce products
that are more elective in nature and were
among the first to be affected by the
recession-driven declines in consumer and
government spending.
Growth in R&D expenditures in Europe
outpaced those in the US (5.9% vs. 4.9%)
to reach €1.7 billion (US$2.5 billion).
Despite a decrease in overall financing
in 2008, overall cash and short-term
investments at year end were only down
9.7% to €6.7 billion (US$9.9 billion) from
the end of 2007. Of course, this was
measured before the full impact of the
financial crisis really took hold in 2009. Of
this figure, roughly 69% of the cash was
being held by 10 companies.
Similar to trends seen in the US public
markets, European medtech stocks had
outperformed broader indices through
the first nine months of 2008 and then
fell sharply in the fourth quarter to finish
down 34.2% for the year – in line with
Europe’s primary indices. In particular, the
aesthetics, oncology and cardiovascular/
vascular segments were hit the hardest,
with each of their aggregate market caps
plunging at least 60%. Through the first
six months of 2009, European medtechs
recovered 10.5% and were outperforming
the CAC 40, the DJ Euro STOXX 50
and the FTSE 100 by a considerable
margin. Unlike the US, no European
segments came close to their year-end
2007 valuation levels by 30 June 2009,
but several segments, including
ophthalmic, nonimaging diagnostics, and
research and other equipment did see
their market caps return to within about
25% of that benchmark value.

Outlook
The remainder of 2009 will continue
to be challenging for many medical
technology companies. In the longer
term, aging populations, longer life
expectancies, expanded elective/lifestyle
medicine, underserved populations
in emerging countries, and continued
product innovations and improvements
should drive long-term expansion of
the industry. Still, the industry faces
significant challenges and a changing
regulatory and competitive landscape.
In addition to the global recession and
decreased provider spending, fundamental
challenges (such as a lengthening FDA
approval process and reimbursement
challenges (including demonstrating
comparative effectiveness) are becoming
increasingly urgent. For small- and
large-cap medtechs to survive and thrive,
they will need to continue to focus on
innovation that drives differentiated
outcomes for patients and on maintaining
fiscal and operational discipline.

A closer look
Here comes the sun: are medtech companies prepared for the
Sunshine Act?

To increase transparency in the financial relationships between physicians
and the pharmaceutical and medical device companies, the US Congress has
introduced the Physician Payments Sunshine Act of 2009, which would require
that companies publicly disclose payments or other value provided to healthcare
professionals, institutions and organizations.
The current version of the Sunshine Act is part of the broader healthcare reform
proposals in Congress. The act would require pharmaceutical and medical
device companies to publicly disclose (1) payments or other consideration given
to healthcare professionals, institutions and organizations in excess of $100
annually and (2) physician ownership interests in applicable manufacturers or
group purchasing organizations. Covered entities would be required to begin their
reporting on 31 March 2011.
Several states also have their own reporting laws, with varying requirements. The
latest draft contains a provision that the federal law would preempt any state laws
that require manufacturers to disclose or report the same information as that
required by the federal law.
While it is still unclear what exactly the final version of any Sunshine Act
legislation will look like, companies are currently facing challenges in meeting the
filing requirements for the various state reports. They are utilizing systems that
aggregate spending from field expense reports and making manual adjustments
to provide the level of detail requested by individual states. It appears that no
company is presently able to comply with the full range of possible pending or
future requirements.
Because of the uncertainty of the future landscape and the potential impact of
preemption, any aggregate spend reporting solution must be flexible and scalable.
Therefore, companies need approaches that will allow them to build in compliance
as an ongoing component of the reporting system as the initiatives evolve.
The financial crisis that ravaged the public markets, as well as uncertainty around healthcare reform in the US, hurt medtech financing in 2008. The amount of capital raised in the US and Europe was down 38% from US$14.7 billion in 2007 to US$9.2 billion in 2008. The US experienced a 53% drop in financing. Europe, on the other hand, enjoyed a 61% increase to a record high of €2.2 billion (US$3.2 billion), largely driven by two companies which were responsible for an upsurge in follow-on offerings, convertible debt and Private Investment in Public Equity (PIPE) transactions. Venture capital – which remained relatively resilient (only down 12% from 2007) – accounted for 47% of financing totals in 2008, while IPO capital all but disappeared, falling 93% during the year.

The financing picture declined further in the first quarter of 2009 before picking up in the second quarter. The industry experienced its lowest quarterly investment in at least a decade in the first quarter of 2009 (US$790 million). While a boom in venture funding brought in US$2.1 billion in the second quarter, the amount raised in the first half of 2009 was still off by 59% compared to the same period in 2008. Venture investment was off 38% and the public and debt markets were virtually nonexistent.

While the medical technology industry is facing one of the chilliest investment climates in years, it is hard to gauge how much of that is the result of macroeconomic conditions and how much is a change of industry-specific fundamentals. With more venture-backed companies in existence as a result of record funding levels in 2006 and 2007, limited exit opportunities, longer development times...
and the prospect of significant healthcare reform, medtech investors face a host of industry-specific challenges independent of the broader recession. In addition, large medtechs and PE firms that have historically played the role of consolidators have been unable to easily access the debt and follow-on offering funds that helped finance much of their acquisition activity in recent years. These conditions have essentially kept would-be acquirers on the sideline and prolonged the holding period for many investors in private, emerging companies. Not surprisingly, VCs are being forced to make difficult decisions about which companies they will continue to fund until a healthier environment for exits returns and which companies they are going to wind down.

US financing — venture dollars keep the market afloat

While the US$6.0 billion invested into US companies in 2008 was down substantially from the record levels witnessed in 2006 (US$14.0 billion) and 2007 (US$12.9 billion), the 2008 total still surpassed the amounts raised annually from 2000 to 2002 and 2004 to 2005. However, the first half of 2009 saw a further 53% decrease in total financing to US$1.8 billion from the US$3.9 billion spent during the same period of 2008. While Q2 2009 (US$1.3 billion) was up substantially over Q1 2009 (US$503 million), it remains to be seen whether that momentum will be sustained during the remainder of the year.

The record level of financing achieved in 2006 and 2007 was driven principally by large debt offerings — more than US$12.6 billion of convertible debt was raised in these two years, accounting for more than 47% of total US financing. In the wake of the financial crisis, it is not surprising to see that the sharp downturn in the debt
market has had such a negative impact on medtech’s overall US financing picture. With the IPO and follow-on markets also hitting hard times, the one constant in this tumultuous period has been the resilience of venture capital. Venture capital dollars made up nearly 59% of total financing in 2008, and a whopping 72% during the first half of 2009, compared to 31% in 2007. Despite a brief reprieve in Q4 2008 and Q1 2009, it appears VCs once again placed their bets in the US medtech sector during Q2 2009. VCs are attracted to the industry because it allows them to diversify their portfolios beyond areas like biotech or IT. However, as John Salveson of Piper Jaffrey cautions (see "Transactions roundtable" on page 40), much of the near-term venture funding is likely to finance the commercial activities of existing portfolio companies. In the long run, he believes that venture funding will be dampened by expensive trials and lower returns.

European financing
At first glance, the record €2.2 billion (US$3.2 billion) invested in Europe in 2008 was rather impressive, especially given the overall tumultuous markets and the deep reduction of financing seen in the US. However, a significant portion of the European financing – approximately 73% or €1.6 billion (US$2.4 billion) – was attributable to Sweden’s Getinge and Germany’s Fresenius SE. Excluding the impact of the Getinge and Fresenius transactions, European financing would have only been €583 million (US$857 million) – a drop of 44% compared to 2007, even after backing out 2007’s one large deal (Arseus Medical’s IPO.)

During the first half of 2009, European financing was only off by 14% from the same period the year before. But unlike

### US financing by quarter

Breakdown of financings over the past six quarters (US$m)

<table>
<thead>
<tr>
<th></th>
<th>Q1 2008</th>
<th>Q2 2008</th>
<th>Q3 2008</th>
<th>Q4 2008</th>
<th>Q1 2009</th>
<th>Q2 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPO</td>
<td>$115</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td></td>
<td>(3)</td>
<td>(0)</td>
<td>(0)</td>
<td>(0)</td>
<td>(0)</td>
<td>(0)</td>
</tr>
<tr>
<td>Follow-on</td>
<td>$4</td>
<td>$319</td>
<td>$502</td>
<td>$22</td>
<td>$51</td>
<td>$274</td>
</tr>
<tr>
<td></td>
<td>(1)</td>
<td>(7)</td>
<td>(5)</td>
<td>(2)</td>
<td>(2)</td>
<td>(2)</td>
</tr>
<tr>
<td>Convertible debt</td>
<td>$248</td>
<td>$820</td>
<td>$28</td>
<td>$15</td>
<td>$58</td>
<td>$5</td>
</tr>
<tr>
<td></td>
<td>(4)</td>
<td>(8)</td>
<td>(9)</td>
<td>(6)</td>
<td>(3)</td>
<td>(3)</td>
</tr>
<tr>
<td>PIPE</td>
<td>$11</td>
<td>$213</td>
<td>$37</td>
<td>$100</td>
<td>$38</td>
<td>$89</td>
</tr>
<tr>
<td></td>
<td>(3)</td>
<td>(13)</td>
<td>(2)</td>
<td>(7)</td>
<td>(4)</td>
<td>(10)</td>
</tr>
<tr>
<td>Venture capital</td>
<td>$1,293</td>
<td>$891</td>
<td>$907</td>
<td>$476</td>
<td>$356</td>
<td>$965</td>
</tr>
<tr>
<td></td>
<td>(92)</td>
<td>(70)</td>
<td>(78)</td>
<td>(39)</td>
<td>(23)</td>
<td>(76)</td>
</tr>
<tr>
<td>Total</td>
<td>$1,671</td>
<td>$2,243</td>
<td>$1,474</td>
<td>$613</td>
<td>$503</td>
<td>$1,333</td>
</tr>
<tr>
<td></td>
<td>(103)</td>
<td>(98)</td>
<td>(94)</td>
<td>(54)</td>
<td>(32)</td>
<td>(91)</td>
</tr>
</tbody>
</table>

Source: Ernst & Young, Capital IQ, Dow Jones VentureSource, Jefferies & Co. and Windhover
Figures in parentheses indicate number of financings.

### European financing by quarter

Breakdown of financings over the past six quarters (€m)

<table>
<thead>
<tr>
<th></th>
<th>Q1 2008</th>
<th>Q2 2008</th>
<th>Q3 2008</th>
<th>Q4 2008</th>
<th>Q1 2009</th>
<th>Q2 2009</th>
</tr>
</thead>
<tbody>
<tr>
<td>IPO</td>
<td>€0</td>
<td>€12</td>
<td>€0</td>
<td>€2</td>
<td>€0</td>
<td>€0</td>
</tr>
<tr>
<td></td>
<td>(0)</td>
<td>(1)</td>
<td>(0)</td>
<td>(3)</td>
<td>(0)</td>
<td>(0)</td>
</tr>
<tr>
<td>Follow-on</td>
<td>€158</td>
<td>€1</td>
<td>€292</td>
<td>€209</td>
<td>€4</td>
<td>€63</td>
</tr>
<tr>
<td></td>
<td>(1)</td>
<td>(4)</td>
<td>(3)</td>
<td>(2)</td>
<td>(3)</td>
<td>(3)</td>
</tr>
<tr>
<td>Convertible debt</td>
<td>€0</td>
<td>€0</td>
<td>€554</td>
<td>€2</td>
<td>€1</td>
<td>€340</td>
</tr>
<tr>
<td></td>
<td>(0)</td>
<td>(0)</td>
<td>(1)</td>
<td>(2)</td>
<td>(1)</td>
<td>(1)</td>
</tr>
<tr>
<td>PIPE</td>
<td>€0</td>
<td>€412</td>
<td>€11</td>
<td>€14</td>
<td>€121</td>
<td>€11</td>
</tr>
<tr>
<td></td>
<td>(0)</td>
<td>(5)</td>
<td>(2)</td>
<td>(4)</td>
<td>(4)</td>
<td>(4)</td>
</tr>
<tr>
<td>Venture capital</td>
<td>€195</td>
<td>€122</td>
<td>€123</td>
<td>€86</td>
<td>€77</td>
<td>€155</td>
</tr>
<tr>
<td></td>
<td>(40)</td>
<td>(32)</td>
<td>(38)</td>
<td>(29)</td>
<td>(30)</td>
<td>(30)</td>
</tr>
<tr>
<td>Total</td>
<td>€353</td>
<td>€547</td>
<td>€980</td>
<td>€313</td>
<td>€203</td>
<td>€569</td>
</tr>
<tr>
<td></td>
<td>(41)</td>
<td>(42)</td>
<td>(44)</td>
<td>(40)</td>
<td>(38)</td>
<td>(38)</td>
</tr>
</tbody>
</table>

Source: Ernst & Young, Capital IQ, Dow Jones VentureSource, Jefferies & Co. and Windhover
Figures in parentheses indicate number of financings.
the US, where VCs were propelling the majority of funding, one convertible debt offering by Smiths Group for €340 million (US$481) accounted for 44% of all funding in H1 2009. Excluding the Smiths Group transaction, total financing in the first half was actually down 52% from the same period in 2008, which is comparable to the US decline. At the end of the day, the European and US financing situations are very consistent.

Venture funding — VCs stay at the table

US venture funding

VCs invested nearly US$3.6 billion in US medtech companies in 2008, just 10% shy of the US$4 billion record set in 2007. In fact, before the global financial crisis took hold during the fourth quarter, medtech venture capital investment was steaming towards another record year in 2008. Even after a lackluster fourth quarter that witnessed only US$476 million in funding, 2008 turned out to be the second best year on record.

The decline of venture investment in Q4 2008 continued into the first quarter of 2009 when just US$356 million was invested in medtech companies, the lowest quarterly result since at least 2000. But things improved dramatically in the second quarter of 2009 as VCs poured US$965 million into the industry – the highest quarterly investment since Q1 2008. While the number of deals (99 through June 2009) was well off the pace of previous years, the average of US$13.3 million per deal was the highest this decade. Of course, only time will tell whether the second quarter’s resurgent venture capital activity is an aberration. But the spike in investment does demonstrate that VCs, unlike most other US investors, have stayed at the table during this downturn.

Biotexion, a Huntsville, Alabama-based diagnostics company had 2008’s largest venture capital deal with US$100 million raised – an amount that is all the more remarkable since it was a first round financing. While there was little known about Biotexion’s clinical and commercial plans, much more was known about the year’s second-largest deal, Minneapolis-based CVRx. The company completed its fifth round of funding for US$84 million and planned to use its proceeds to complete the pivotal trial and commercialization activities of its Rheos System, an implantable device designed to control hypertension.

Overall, there were nine deals in excess of US$40 million in 2008 (down from 15 in 2007), and four more through the first half of 2009. Similar to the trends seen through the decade, cardiovascular/vascular therapeutic devices and nonimaging
diagnostic companies attracted the lion’s share of venture investment in 2008 and the first half of 2009. Leading the charge in 2009 was New York City-based Small Bone Innovations which announced two venture deals in late June worth a total of US$144 million. A provider of orthopedic products and technologies to treat trauma and diseases in small bones and joints, Small Bone Innovations completed a Series C financing for US$36 million, as well as a Series D financing for US$108 million, which included investments from existing VCs as well as Goldman Sachs and several sovereign wealth funds. The proceeds were used in part to complete the acquisition and US launch of the Scandinavian Total Ankle Replacement system.

European venture funding

European medtechs received €525 million (US$772 million) in venture financing in 2008. While this figure was down 25% from the €699 million (US$958 million) invested in 2007, it was comparable to levels seen between 2004 and 2006. And even though venture funding continued to slide – falling 27% in the first half of 2009 (€231 million or US$327 million) compared to the same period in 2008, the second quarter amount of €154 million (US$218 million) was the highest quarterly venture capital total since the first quarter of 2008, indicating a recovery may be at hand. Overall, European imaging and nonimaging diagnostics companies garnered the most investments by VCs in 2008 and the first half of 2009, which was consistent with trends seen since 2004.

ApaTech of the UK, a developer of bone graft technologies, was the recipient of a US$45 million (€30.6 million) funding in March 2008 – the largest European venture capital deal of the year. The late-stage round was to be used to further...
the clinical development of its Actifuse technology, as well as to significantly expand manufacturing capacity. A maker of electrical therapies for the treatment of chronic heart failure, Netherlands Antilles-based Impulse Dynamics received the largest venture investment through the first half of 2009 — €27 million (US$38 million). Of the top 10 deals in 2008 and the first half of 2009, three went to companies based in Israel. Since 2004, Israel has led all European countries in total venture financing with €711 million (US$1.1 billion), and has emerged as a consistent hotbed of early-stage medtech companies. (For more on Israel’s success, see “A closer look” on page 39.)

A changing VC investment model
VCs have historically been attracted to medtech because of global demographic trends, regulatory-approval and reimbursement timelines that are shorter than those for pharmaceuticals or biologics, and the prospect of exit via an acquisition by one of many strategic buyers. However, the recession, impending healthcare reform in the US, and the changing regulatory and reimbursement environment are putting pressure on the venture funding model that has existed to date.

During the first half of this decade, VCs seemed to have found a decent balance between investments and exits. From 2000 to 2005, VCs invested, on average, just over $2 billion per year into US-based medtechs. But between 2006 and 2008 the average annual amount of investment ballooned to $3.6 billion per year and medtech’s share of total venture capital investment nearly doubled. During this time, the average size of rounds and the


### Top 10 US venture rounds of 2008 and the first half of 2009

Small Bone Innovations raises largest round

<table>
<thead>
<tr>
<th>Company</th>
<th>Location</th>
<th>Product type (disease)</th>
<th>Gross raised (US$m)</th>
<th>Quarter</th>
<th>Round</th>
</tr>
</thead>
<tbody>
<tr>
<td>Small Bone Innovations</td>
<td>New York, N.Y.</td>
<td>Therapeutic devices (orthopedic)</td>
<td>$108</td>
<td>Q2 2009</td>
<td>4</td>
</tr>
<tr>
<td>Biotexion</td>
<td>Huntsville, Ala.</td>
<td>Nonimaging diagnostics</td>
<td>$100</td>
<td>Q1 2008</td>
<td>1</td>
</tr>
<tr>
<td>CVRx</td>
<td>Minneapolis, Minn.</td>
<td>Therapeutic devices (cardiovascular/vascular)</td>
<td>$84</td>
<td>Q3 2008</td>
<td>5</td>
</tr>
<tr>
<td>TriVascular2</td>
<td>Santa Rosa, Calif.</td>
<td>Therapeutic devices (cardiovascular/vascular)</td>
<td>$65</td>
<td>Q1 2008</td>
<td>1</td>
</tr>
<tr>
<td>Cameron Health</td>
<td>San Clemente, Calif.</td>
<td>Therapeutic devices (cardiovascular/vascular)</td>
<td>$52</td>
<td>Q2 2008</td>
<td>5</td>
</tr>
<tr>
<td>Valeritas</td>
<td>Parsippany, N.J.</td>
<td>Therapeutic devices (hematology/renal)</td>
<td>$51</td>
<td>Q4 2008</td>
<td>1</td>
</tr>
<tr>
<td>Novasys Medical</td>
<td>Newark, Calif.</td>
<td>Therapeutic devices (urology/pelvic)</td>
<td>$50</td>
<td>Q2 2008</td>
<td>6</td>
</tr>
<tr>
<td>PhotoThera</td>
<td>Carlsbad, Calif.</td>
<td>Therapeutic devices (neurology)</td>
<td>$50</td>
<td>Q2 2009</td>
<td>3</td>
</tr>
<tr>
<td>Pathway Medical Technologies</td>
<td>Kirkland, Wash.</td>
<td>Therapeutic devices (cardiovascular/vascular)</td>
<td>$43</td>
<td>Q2 2009</td>
<td>8</td>
</tr>
<tr>
<td>Zounds</td>
<td>Mesa, Ariz.</td>
<td>Therapeutic devices (ENT)</td>
<td>$41</td>
<td>Q2 2008</td>
<td>2</td>
</tr>
</tbody>
</table>

Source: Ernst & Young, Capital IQ, Dow Jones VentureSource and Windhover
Amount raised by Small Bone Innovations includes unspecified financing from Goldman Sachs and several sovereign funds
number of rounds also began to escalate. From 2000 to 2005, the average venture capital round was US$9.6 million; however, this figure increased 23% to US$11.8 million from 2006 to 2008. During these same periods, the average number of total rounds went up 42% from 212 to 302. A similar story unfolded in Europe. Europe saw a 70% increase in total venture investment between 2004 and 2007, while average round sizes nearly doubled from €2.6 million (US$3.8 million) in 2004 to €5.0 million (US$7.4 million) in 2007 — these averages subsequently dropped to €3.9 million (US$5.7 million) in 2008.

This increased amount of capital was certainly great news for medtech entrepreneurs, but the proliferation of new companies and new technologies may have made it harder for VCs to fully evaluate companies, as they did in the past, and then differentiate them to acquirers. While there was a surge of IPOs in Europe in 2006 and 2007, the rate of IPOs in the US remained at about 10 per year this decade. Combined with a flat level of acquisitions of venture-backed companies during this entire period across the US and Europe, it became clear that there weren’t enough exits for all of the new money flowing into the industry. In other words, the venture funding model was being squeezed.

At the same time, the industry’s traditional advantages – shorter, less expensive innovation and commercialization cycles and straightforward regulatory and reimbursement pathways – have come under increased strain. With a host of financial and regulatory issues on the table, there seems to be greater unpredictability for venture-backed medtechs than ever before. US FDA clinical trials in support of Premarket Approval (PMA) filings are becoming more common and government and private payors are becoming more stringent on reimbursement. A venture funding model that was built on a relatively modest total investment of roughly US$50 million and a relatively quick

### Top 10 European venture rounds of 2008 and the first half of 2009

**Synthetic bone graft maker ApaTech takes in top VC investment**

<table>
<thead>
<tr>
<th>Company</th>
<th>Country</th>
<th>Product type (disease)</th>
<th>Gross raised (£m)</th>
<th>Quarter</th>
</tr>
</thead>
<tbody>
<tr>
<td>ApaTech</td>
<td>United Kingdom</td>
<td>Therapeutic devices (orthopedic)</td>
<td>€33.8</td>
<td>Q1 2008</td>
</tr>
<tr>
<td>Impulse Dynamics</td>
<td>Netherlands</td>
<td>Therapeutic devices (cardiovascular/vascular)</td>
<td>€27.2</td>
<td>Q2 2009</td>
</tr>
<tr>
<td>Mauna Kea</td>
<td>France</td>
<td>Imaging</td>
<td>€25.0</td>
<td>Q1 2008</td>
</tr>
<tr>
<td>Technologies</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>BrainsGate</td>
<td>Israel</td>
<td>Therapeutic devices (neurology)</td>
<td>€22.9</td>
<td>Q3 2008</td>
</tr>
<tr>
<td>Cellectricon</td>
<td>Sweden</td>
<td>Research and other equipment</td>
<td>€20.7</td>
<td>Q1 2008</td>
</tr>
<tr>
<td>SuperSonic Imagine</td>
<td>France</td>
<td>Imaging</td>
<td>€20.0</td>
<td>Q4 2008</td>
</tr>
<tr>
<td>Spectrum Dynamics</td>
<td>Israel</td>
<td>Imaging</td>
<td>€18.8</td>
<td>Q2 2009</td>
</tr>
<tr>
<td>superDimension</td>
<td>Israel</td>
<td>Imaging</td>
<td>€15.2</td>
<td>Q2 2008</td>
</tr>
<tr>
<td>Symetis</td>
<td>Switzerland</td>
<td>Therapeutic devices (cardiovascular/vascular)</td>
<td>€14.9</td>
<td>Q2 2009</td>
</tr>
<tr>
<td>BoneSupport</td>
<td>Sweden</td>
<td>Therapeutic devices (orthopedic)</td>
<td>€12.9</td>
<td>Q3 2008</td>
</tr>
</tbody>
</table>

*Source: Ernst & Young, Capital IQ, Dow Jones VentureSource and Windhover*
exit via an acquisition may now require more than US$100 million just to get through a PMA-supporting clinical trial program. This change will impact returns, reduce the number of venture-backed companies and likely lead to a change in the types of companies the VCs choose to back. Depending on the technology, it may encourage the adoption of an Outside-the-US, or OUS, strategy. An OUS strategy typically involves (more limited) clinical trials and a product launch in European markets before proceeding to the US. This strategy was adopted with great success by California-based CoreValve which bypassed the US market altogether, yet accepted a greater than US$700 million take-out offer from Medtronic. VCs may also prefer to back companies that can demonstrate the ability to generate revenue earlier in their development cycles.

Despite these challenges, due to demographic trends, unmet medical needs and a proliferation of exciting new technologies, medtech will continue to be an important industry for VCs. As a result of reduced access to capital across the economy, we expect overall venture investments to decline, but medtech should continue to garner a steady percentage of total venture investments in the 10 to 13% range. Venture capital investments in the short run will largely be targeted to existing portfolio companies, or other late-stage companies that are close to commercialization.

These realities will force emerging medtech companies to operate more efficiently as companies will need to meet technical and business objectives with less capital and over longer time horizons. Until the IPO environment improves, companies will need to cast their fundraising net wider and be prepared to reset their valuation expectations.

IPOs

US perspective – IPOs
The US medtech industry has not witnessed an IPO since the first quarter of 2008. As we go to press, this five-quarter dry spell is the longest experienced since 2003, which also lasted five quarters (from August 2002 to February 2004). While the disappearance of medtech IPOs in 2003 was attributed to the overall lack of investor enthusiasm for the field, this most recent dearth of IPOs has resulted more from the systemic issues impacting the capital markets.

A closer look

Alternative financing – government incentives

At a time when many medtech companies are struggling to raise capital for their operational needs, firms are becoming creative and looking beyond traditional sources of funding. In this challenging climate, government incentives can provide welcome injections of cash or relief through tax savings or subsidies. And while many state and local governments are under heightened budgetary pressure in this downturn, attracting and retaining medtech companies remains a priority for economic development agencies.

Incentives are often keyed to specific metrics such as workforce expansion or retention, new capital investments, R&D spending and/or employee training. As such, companies should explore their incentives options any time they make significant investments or undertake business expansions or consolidations. While incentives are not likely to be the sole driver of a capital investment decision, they should be evaluated when choosing the location and scope of new investments. In reviewing potential incentives, companies should consider the monetary benefit that each program can provide, the impact of an incentives application process on the overall project timeline and the compliance requirements of each program. This analysis should be done throughout the site selection and investment process.

Not all incentive programs may be relevant. For instance, while many jurisdictions offer income tax-based credits, these are not very valuable for medtech companies that are not currently in an income tax position. Other incentives, such as direct financing, cash grants or abatements for property, sales or use tax may provide greater immediate value.

Like all money, these funds come with some strings attached. Most incentives programs require formal agreements between governments and the companies receiving funding. These agreements list the specific levels of job creation, capital investment and/or job training that a company commits to make in exchange for a specified incentives package. If a company fails to meet its commitments, many jurisdictions reserve the ability to retract or “claw back” the incentives.
While CardioNet, MAKO Surgical and Lifeline Scientific were able to raise an aggregate of US$115 million in IPOs during the first quarter of 2008, 16 additional companies that were in registration have pulled their filings since the beginning of 2008. Many of these 16 companies had achieved technical, regulatory and financial milestones necessary to enter the public markets under normal conditions. The road to an IPO is also lengthening. Between 2000 and 2002, on average it required 5.5 years and $48.8 million in venture funding to go public. From 2006 to 2008, those same indicators inflated to 9.7 years and $62.1 million. While CardioNet’s long journey to an IPO (14 years and US$168 million in venture capital funding) certainly skewed the 2006–2008 averages, these trends would still be borne out even in the absence of the CardioNet IPO.

One bright spot for these recently public companies has been the availability of capital from venture investors. Companies like EnteroMedics, MAKO Surgical, Nanosphere and TomoTherapy have closed Venture Investment in Public Entities (VIPE) transactions as the result of having relatively attractive valuations for their stage of development as compared to private companies who are competing for capital.

European perspective – IPOs
Similar to the US, the European IPO market has all but disappeared since the end of 2007. There were only two IPOs in 2008. Ipsogen, a French oncology diagnostic company, went public in the second quarter, raising €11.8 million (US$17.4 million), and German contact lens manufacturer LensWista raised €1.5 million (US$2.2 million) in the fourth quarter. This performance came on the heels of two very impressive years for IPOs in Europe. European medtech companies raised €569 million (US$782 million) in 21 IPOs in 2006 and €487 million (US$667 million) in 17 IPOs in 2007. In both of these years, IPOs represented nearly a third of all European funding, and they offered a viable exit to the increasing number of emerging companies receiving venture funding.

The path to an initial public offering – US
Today’s VC-backed medtechs require more time and money to go public

![Graph showing average VC investment and average years to IPO over time.](source: Ernst & Young, Capital IQ, ThinkEquity and Windhover)

US perspective – other financing
Throughout 2006, 2007 and the first half of 2008, relatively easy access to capital helped numerous companies finance acquisitions and expansions and strengthen their balance sheets. Since the second half of 2008, proceeds from convertible debt, follow-on public offerings and PIPE transactions have dropped sharply.

In 2006 and 2007, over US$12.6 billion of convertible debt was raised by public medtech companies like Beckman Coulter, Hologic, Medtronic (which alone raised US$4.4 billion in 2006), and St. Jude Medical. In 2008, only US$1.1 billion was raised via convertible debt – representing a more than 80% decline from the prior year. However, even more astonishing was the further decline over the past four quarters. From July 2008 through June 2009, just over US$100 million was raised with only US$4.7 million in the second quarter of 2009. Texas-based Kinetic Concepts’ (KCI) US$690 million offering was responsible for the lion’s share of convertible debt in 2008. KCI used the majority of the proceeds to help fund its US$1.7 billion acquisition of wound management company LifeCell Corporation in April 2008. Other than NuVasive’s US$230 million convertible debt offering in March 2008, there was no other...
Mass exodus – 16 US IPOs withdrawn since 2008

<table>
<thead>
<tr>
<th>Company</th>
<th>Location</th>
<th>Product type (disease)</th>
<th>Month pulled</th>
<th>Filing size (US$m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BG Medicine</td>
<td>Waltham, Mass.</td>
<td>Nonimaging diagnostics</td>
<td>January 2008</td>
<td>$80</td>
</tr>
<tr>
<td>Concentric Medical</td>
<td>Mountain View, Calif.</td>
<td>Therapeutic devices (cardiovascular/vascular)</td>
<td>February 2008</td>
<td>$69</td>
</tr>
<tr>
<td>Transoma Medical</td>
<td>St. Paul, Minn.</td>
<td>Nonimaging diagnostics</td>
<td>February 2008</td>
<td>$75</td>
</tr>
<tr>
<td>MonoSol Rx</td>
<td>Warren, N.J.</td>
<td>Therapeutic devices (non-disease-specific)</td>
<td>March 2008</td>
<td>$68</td>
</tr>
<tr>
<td>Emphasys Medical</td>
<td>Redwood City, Calif.</td>
<td>Therapeutic devices (respiratory)</td>
<td>May 2008</td>
<td>$86</td>
</tr>
<tr>
<td>Broncus Technologies</td>
<td>Mountain View, Calif.</td>
<td>Therapeutic devices (respiratory)</td>
<td>June 2008</td>
<td>$86</td>
</tr>
<tr>
<td>Noninvasive Medical</td>
<td>Las Vegas, Nev.</td>
<td>Nonimaging diagnostics</td>
<td>June 2008</td>
<td>$53</td>
</tr>
<tr>
<td>Salient Surgical</td>
<td>Portsmouth, N.H.</td>
<td>Therapeutic devices (non-disease-specific)</td>
<td>August 2008</td>
<td>$86</td>
</tr>
<tr>
<td>Fluidigm</td>
<td>S. San Francisco, Calif.</td>
<td>Research and other equipment</td>
<td>September 2008</td>
<td>$86</td>
</tr>
<tr>
<td>X Dx</td>
<td>Brisbane, Calif.</td>
<td>Nonimaging diagnostics</td>
<td>September 2008</td>
<td>$86</td>
</tr>
<tr>
<td>Cardiovascular Systems</td>
<td>St. Paul, Minn.</td>
<td>Therapeutic devices (cardiovascular/vascular)</td>
<td>November 2008</td>
<td>$86</td>
</tr>
<tr>
<td>Acclarent</td>
<td>Menlo Park, Calif.</td>
<td>Therapeutic devices (ENT)</td>
<td>December 2008</td>
<td>$86</td>
</tr>
<tr>
<td>Biotrove</td>
<td>Woburn, Mass.</td>
<td>Research and other equipment</td>
<td>December 2008</td>
<td>$75</td>
</tr>
<tr>
<td>TransMedics</td>
<td>Andover, Mass.</td>
<td>Therapeutic devices (hematology)</td>
<td>December 2008</td>
<td>$86</td>
</tr>
<tr>
<td>Zonare Medical Systems</td>
<td>Mountain View, Calif.</td>
<td>Imaging</td>
<td>December 2008</td>
<td>$86</td>
</tr>
<tr>
<td>TherOx</td>
<td>Irvine, Calif.</td>
<td>TD (cardiovascular/vascular)</td>
<td>February 2009</td>
<td>$100</td>
</tr>
</tbody>
</table>

Source: Ernst & Young, DeviceSpace, Jefferies & Company and MSN Money
Percent change in market cap

European IPO performance – Classes of 2007 and 2008
Percent change in market cap

Source: Ernst & Young
financing over US$75 million in 2008 or the first half of 2009.

While not as grim a story as convertible debt, follow-on offerings and PIPE investments also experienced significant drops over the past 18 months. Close to US$847 million (down 45% from 2007) was generated from follow-on offerings in 2008, 40% of which was raised by analytical tool developer Illumina in August 2008. After only US$72 million was raised in the fourth quarter of 2008 and the first quarter of 2009, Beckman Coulter sold 4.5 million shares (for US$238.5 million) in May to help finance the acquisition of Olympus’ diagnostic systems business. Overall, through the first half of 2009, US$324 million in follow-on funding had been raised – still 25% off the pace of H1 2008. On the PIPE front, US$360 million (down 11% from 2007 and the lowest annual amount since 2002) was raised in 2008, and the pace fell further in the first six months of 2009, which saw only US$127 million of proceeds. Given the weakness and volatility of the public markets, heavy investment via PIPEs is not expected through the remainder of 2009.

European perspective – other financing

In Europe, total financing was largely driven by follow-on offerings and convertible debt. But, as discussed earlier, most of this financing was driven by two companies: Getinge and Fresenius Medical. As a result of these transactions, follow-on offerings increased from €1.1 billion (US$1.5 billion) in 2007 to €6.6 billion (US$9.7 billion) in 2008, while convertible debt grew from €2.2 billion (US$3.0 billion) in 2007 to €5.57 billion (US$8.19 billion) in 2008. PIPE financings shot up 210% in 2008 to €4.4 billion (US$6.4 billion) – the highest amount seen since 2004. Unlike the US, where these financing vehicles had been common, issuances of follow-on equity and convertible debt instruments had been infrequent in Europe in recent years. In fact, from 2004 to 2007, cumulative follow-on offerings totaled only €2.67 billion (US$3.93 billion), while convertible debt aggregated €5.8 billion (US$8.53 billion).

As mentioned earlier, Germany’s Fresenius SE and Sweden’s’ Getinge were jointly responsible for 73% of 2008’s €2.2 billion in total financing. Each company used its proceeds to make sizeable acquisitions in the third quarter of 2008. Fresenius used a variety of convertible debt, follow-on and PIPE financings to raise more than €1.2 billion (US$1.8 billion) to acquire US-based APP Pharmaceuticals, a marketer of generic injectable drugs, for US$3.7 billion (€2.5 billion). Getinge employed two follow-on offerings totaling €3.64 billion (US$5.35 billion) to help finance its acquisition ofDatascope for US$8.65 billion (€5.88 billion).

Through the first half of 2009, €677 million (US$959 million) had been raised in follow-ons, €3.41 billion (US$4.82 billion) in convertible debt and €1.32 billion (US$1.87 billion) in PIPEs. Each of these totals was well below levels achieved during the comparable period in 2008.

Outlook

While the funding environment for medtech companies will likely remain uncertain for the foreseeable future, there is reason to be cautiously optimistic. With the number of patients and procedures rising, particularly in emerging markets where healthcare expectations and expenditures are on the rise, long-term growth prospects should attract investors. However, significant challenges in the form of increased efforts around cost containment, stretched hospital budgets and healthcare reform may mute these trends.

In the shorter term, medtech funding will likely recover once the broader public markets recuperate. However, with almost no IPO market in the first half of 2009,
a full recovery will likely take more than a few months or quarters. Any recovery will need to include improved consumer and investor confidence, as well as an opening of the credit and debt markets to credible, cash flow-positive companies. Once this occurs, we should begin to see more follow-on and debt funding flow into medtech, and eventually investor interest will trickle down to the IPO market. In the interim, expect to see a sustained flow of funds from an increasingly selective VC community, as well as a backlog of solid IPO candidates — many of whom will remain targets of acquirers.

---

**A closer look**

**Israel leads venture funding in Europe**

Since 2004, Israeli medtechs have received more than €700 million (US$ 1 billion) in venture capital funding — more than any other country outside the US, and just one indicator of the country’s vibrant and innovative medtech industry. Why has Israel’s medtech sector been so successful, and what challenges does it face in the current environment?

The favorable landscape for medtech investment can be traced back to the rapid development of Israel’s high-tech field that began in the 1990s. Generous government funding and venture capital helped young entrepreneurs set the foundation for rapid growth and innovation within the high-tech industry. This created an infrastructure for medtech entrepreneurship that has allowed the industry to bloom over the past decade. This infrastructure includes:

- **Human resources:** university-based professionals and experienced scientists conducting research, as well as hospital-based physicians and professors who combine practical experience with awareness of what the market needs. Physicians also show great openness to innovation and are early adopters of cutting-edge technologies.

- **Patents:** Israel is ranked number one in the world for medical device patents per capita and seventh in the absolute number of medical device patents.

- **Government support:** funding is granted to medtech entrepreneurs through various vehicles such as royalty-bearing R&D grants, scientific incubators, binational funds and tax holidays geared toward medtech operations.

Historically, Israeli entrepreneurs have also performed feasibility studies in less time and with smaller budgets than their counterparts in the US and Europe. As a result, many new medtech start-ups are established each year. However, the challenge that Israeli entrepreneurs face is the transition to the later stages: orderly clinical trials, manufacturing and marketing. At these stages, an experienced Chief Executive Officer (CEO) is needed to guide and finance the company’s growth and to build clinical, commercial and business development capabilities. While a new generation of skilled and experienced Israeli CEOs has developed in the last decade, the demand for them still exceeds their supply.
Transactions roundtable

Deal-making in uncertain times

Medtech has always been a deal-driven industry. Emerging companies have long relied on M&A for exits, while established companies have turned to transactions to bolster pipelines and revenues. Yet, after several years of impressive activity, medtech deal-making has fallen sharply since the onset of the global financial crisis. Many would-be acquirers are grappling with financial austerity, tight credit markets, challenging valuations and uncertainty around proposed healthcare reforms in the US.

To better understand the current deal-making climate, we sat down in the fall of 2009 with representatives from five companies that are veterans of the medtech deal environment. These include business development executives from three medtech firms that have been among the most acquisitive in recent years — Covidien, Johnson & Johnson and Medtronic. Our panel also includes insights from an investment banker from Piper Jaffrey with more than 20 years of medtech transaction experience — and the Private Equity (PE) house of GTCR Golder Rauner.

The picture that emerges is of a deal space that has been affected by tremendous uncertainty, and the panelists offer various perspectives on the deal-related challenges now facing the sector. Despite these obstacles, however, they all remain bullish on the sector’s long-term potential for strategic investors, financial investors — and patients.

Ernst & Young: How is the current financial crisis affecting the medtech M&A market? Have we experienced similar challenges in the past, or are things different this time?

Salveson: I do think we’ve been here before. It feels eerily similar to what we experienced in 1993 and 1994. Back then, deal volume had dried up and publicly held medtechs were getting crushed in the market. There was uncertainty about where the industry was going. While the issues are a little different today, there is no question that the number of deals has declined just as it did back then. Today’s strategic acquirers have become very selective about the deals they are willing to do. They are focusing very little on new platforms and are much more interested in buttressing their existing platforms.

Cornell: I agree with Jon. Companies across the industry have been affected by the financial crisis, and they are definitely more focused on increasing operating efficiency to get through this downturn. I think medtech and M&A activity will recover when the broader economy recovers, and we will see some systemic changes that may permanently alter the landscape. The downturn has also diminished the appetites of small- and mid-cap firms since they can’t use their equity as readily to perform deals.
Wendell: One obstacle right now is the valuation gap—some companies’ expectations about valuations and multiples are unchanged from a year or two ago. At the same time, many smaller firms still don’t fully appreciate that it’s going to require more clinical data, time and money to launch products than ever before.

Stockburger: Like Amy, I think valuation has been the biggest challenge over the past year. At the beginning of the crisis, as valuations plummeted, many companies—both public and private—were hesitant to approach big buyers because of the tumultuous change and tremendous uncertainty. Now, things are settling a bit and management teams are adjusting to the new realities of a closed IPO market and scarce private funding. Companies that once were very reluctant to talk to large buyers are calling, because easy funding options have all but disappeared.

Ernst & Young: With a closed IPO market, M&As are the only viable exit for Venture Capitalists (VCs). With a slowdown in M&A activity, will VCs and other private investors remain bullish on medtech? Is there enough appetite from acquirers to sustain the current level of funding?

Cornell: VCs are looking at their portfolios and the capital they have on hand, and they’re doing the cold, hard calculus of where they are going to place their bets. I think they will be increasingly reluctant to fund pre-revenue medtechs, which still face big clinical risks. Going forward, the Food and Drug Administration (FDA) will require more clinical evidence to approve devices. In the past, VCs could invest US$30 million in a company and expect an exit with a decent return. In the future, they may need to invest more than US$100 million to conduct a PMA study. This is certainly a change in the model. VCs will either need to invest larger sums to access big markets or will have to be content focusing on 510(k)s or selling their PMA technologies at an earlier point. Either way, venture returns probably will be lower.

There will be a shakeout in the VC industry. It was overcapitalized and you had too much money chasing too few deals—or at least chasing too much of the same thing. Money will be reallocated and some firms will exit the industry altogether. However, in the long term, I think medtech is still going to be a good area for venture capital. VCs have specialized knowledge, and their model of funding early, risky opportunities works very well. But with concerns over comparative effectiveness and FDA mandates, I think VCs are going to leave the PMA-type development to the big companies.

“Management teams are adjusting to the new realities of a closed IPO market and scarce private funding. Companies that once wouldn’t even talk to large buyers are calling, because easy funding options have all but disappeared.”

Wendell: Even though the levels of investment are lower than in the 2006–2008 timeframe, Q1 and Q2 medtech venture funding levels are similar to the levels seen from 2001 to 2005. I think this is a pretty reasonable level of investment and medtech will continue to attract investors. A large corporation like Covidien can’t develop all of its technology internally, so we will always need to go out and find technologies—and VCs know that. The key to their future success will be to know where to invest and to identify markets that will be rewarded for innovation, patient outcomes and adding value to the healthcare system. They’ll need to look at technologies with more of a critical eye. Is this a good market? Does it have a good regulatory pathway and is it going to get reimbursement?

Salveson: I don’t think there is enough appetite in the M&A market to sustain investment levels. While there are many companies that can, and will, ultimately acquire smaller medtech firms, there are many others that won’t. VCs are worried about survival and liquidity, and right now they’re reserving capital to primarily focus on existing portfolio companies. So while we will see continued VC investment in the short run—because many of these companies will need funding into their commercialization phases—the longer, more expensive trials, larger rounds and lower returns will reduce VC investment in the long run.

Stockburger: I guess I look at things a little differently from Chad and Jon. While we’ve definitely received panic calls from companies that couldn’t raise the money they expected to raise, we’ve also seen others raising more money than anticipated. Right now, I think access to funding depends upon your proposition. Companies that are early in the life cycle and don’t have revenues will face rough waters, while those that are further along in their evolution—and have revenues—are finding it easier because they are perceived as safer bets.
Ernst & Young: What key drivers — therapeutic area, strategic fit, revenue and growth, diversification, etc. — are currently most important to strategic acquirers?

Wendell: Covidien makes sure that the products we develop and bring to market improve patient outcomes and deliver value to the healthcare system. So when we look to acquire a company, we make sure we can prove that the target's technology is both strategic and will add value to the healthcare system.

When we looked at acquiring small start-ups in the past, a majority of our due diligence was spent on Intellectual Property (IP). If the company didn't own its IP, didn't have a good IP strategy or infringed on IP, the deal would quickly fall apart. Today, in addition to IP, we spend a great deal of time evaluating the value proposition associated with a company and its technology. What is the reimbursement story? Can you demonstrate cost savings and improved patient outcomes? How are you going to sell and promote the technology? Acquirers have become more rigorous, and given the fact that it will take more time and money to bring a product to market – and who knows what happens with healthcare reform – I think we will see fewer VC-backed properties that meet the standards of larger buyers.

Cornell: Medtronic is focusing on technologies that will deliver better, less-invasive therapeutic outcomes and save money for the healthcare system. We've recently made big bets on two early-stage companies involved with percutaneous valves and arterial fibrillations – technologies we think will be game-changers in their respective therapeutic areas. Other hot areas right now – for good reason – are neurologic, diabetes and minimally invasive spine technologies.

Ernst & Young: Over the past five years, we saw PE investors enter the medtech space, but investment levels dropped significantly last year. Will medtech continue to be an attractive investment for PE?

Mihas: PEs will continue to be attracted to medtech. But with less access to financing, many have become more selective. Instead of buying high-flying, high-growth companies, they may target underperforming assets – such as a neglected or low-growth division within a big company. By focusing on margins and manufacturing or operating efficiencies, PEs can kick-start growth and create value in properties that didn't entirely fit the operating model of the parent company.

Stockburger: I agree with Dean. I think PE is always going to be a player in the medtech industry. While they seemed willing to take some risks in the past, I think PEs will now be looking for safer bets – companies with solid, well-performing businesses.

Salveson: With a lack of financial leverage and all of the macro issues swirling around the medtech industry, PEs are reevaluating their strategies and recalibrating their return requirements – they're thinking much more about deal structures. In our opinion, there are only a handful of players that have the expertise to play in this risky, highly regulated arena for the long term. That being said, the industry has been a very profitable place for some PEs, and a handful of high-quality PE firms remain committed and equipped to perform medtech transactions. While we are no longer in the world of highly leveraged billion-dollar transactions, I think there is a very interesting middle-market opportunity for PEs that are willing to place a lot more equity into transactions than in the past and are also willing to partner as opposed to being 100% shareholders.

Wendell: PE is still definitely out there looking. However, unlike two years ago, securing funding for deals is challenging. For instance, right now we are considering a handful of divestitures. We've been discussing one property with PE firms, but they have been unable to secure the financing, and I am very concerned about their ability to get the deal done.
Ernst & Young: In December 2007 the Financial Accounting Standards Board issued Statement No. 141(R), which significantly changes US rules on accounting for acquisitions. What impact has 141(R), and specifically changes around in-process R&D and contingent consideration, had on your acquisition strategy?

Cornell: While we're definitely paying a lot of attention to 141(R), it's not affecting whether we do deals or not. Since there isn't a lot of experience to draw on, there's a high degree of judgment on how to actually implement the rules. The bigger question is whether markets will simply disregard the impact of 141(R) or whether they will punish companies for earnings hits that are attributable to ongoing acquisition write-offs. Companies conducting several acquisitions may have significant charges or gains that could obfuscate the underlying performance of the business. At this point, I don't think anybody knows how things will pan out.

Wendell: Similar to what Chad said, it's definitely on our minds. We've been spending a great deal of time understanding how 141(R) will impact our deal strategy going forward and also how our competitors are addressing it. While this situation has yet to shake out, we have seen a number of large-company acquirers ending milestone payments – they're including the probability-adjusted present value of those payments in the purchase price. Ideally, we want to use milestones as infrequently as possible, though we recognize that they may be needed occasionally to bridge valuation gaps.

Salveson: I think it has definitely affected the market. We saw a real rush to action in the third and fourth quarter of 2008. 141(R) is impacting the thinking of some large medtech players from doing an early-stage transaction. From a purely financial standpoint, these deals now look less attractive than they did a year ago because the transaction is now being fully burdened. There is a higher uncertainty of how the long-term ramifications are going to play out.

Mihas: From a PE standpoint, we're concerned with cash flows and the ability to service and pay down debt, so whether R&D is on the balance sheet or the income statement isn't super relevant to us. However, when you're taking a company public and worried about EPS and multiples, then R&D does get a little trickier and 141(R) would have an impact.

Ernst & Young: With regard to transactions, what is your biggest concern with the healthcare reforms currently being considered in the US? Which will have the most positive and negative impact on medtech acquirers and sellers?

Stockburger: The uncertainty of what healthcare reform is actually going to look like is what worries us when we are looking at a transaction. Our biggest concern is that an issue we haven't even thought of yet could somehow unexpectedly impact the new business. It's really difficult to forecast the potential impacts and you can get so caught up in it the analysis that you don't do any deals. Still, healthcare reform is certainly impacting the way we look at transactions – we do our best to incorporate our views when looking at transactions in order to develop the most appropriate valuation.

Salveson: With Department of Justice, FDA and reimbursement issues hanging over the industry, I think it's safe to say that the government is going to have a lot of input on the healthcare system going forward. Everyone seems worried about the very real possibility of a large-scale reimbursement pullback. We saw

“PEs will continue to be attracted to medtech. But with less access to financing, many have become more selective. Instead of buying high-flying, high-growth companies, they may target underperforming assets — such as a neglected or low-growth division within a big company.”
a similar situation in the early 1990s, when the proposed Clinton healthcare plan pretty much placed all transactions on ice. In these situations, perception is as bad as reality, and I think all of the current chatter and uncertainty is having a very negative impact on M&A activity.

Wendell: While we believe all Americans should have access to healthcare, we are concerned that if universal coverage is accompanied by reductions in payments, then access to high quality care and technologies could be restricted.

We believe Comparative Effectiveness (CE) is one way to show value for technologies, and even though we have a ways to go before we see the benefits of CE via the necessary research, it confirms our need to ensure that the technologies we acquire and develop internally truly do add value to the system through better patient or procedural outcomes.

Ernst & Young: With an air of uncertainty over the economy and healthcare reform, what deal trends and developments do you see over the next 12 to 24 months? What will be their long-term implications on transactions within medical technology?

Salveson: In the past, deals – especially for large companies – have been mainly about driving growth. However, I think the focus of strategic acquirers has changed a bit. Today, M&A is no longer the only means for driving growth – companies are also increasingly focused on cash flow, capitalization and portfolio management. It’s all about efficient technology development and streamlined commercial operations. Finally, I think we’re going to see some healthy consolidation of smaller players by bigger players.

Cornell: The uncertainty of healthcare reform and the potential impact of issues such as comparative effectiveness and reduced reimbursements are keeping people on the sidelines. However, acquirers also can’t escape the many positives of the industry. The population in the US and Europe is getting older, and that will drive a greater need for healthcare. Emerging markets such as Brazil, Russia, India and China will experience rising demand for medical technologies as incomes increase. And medical technologies are only going to get better. Even though the healthcare system will change, technologies that deliver superior clinical outcomes at a reasonable cost will secure reimbursement and capture market share. How healthcare companies are paid, and at what level they’re paid, are definitely near-term risks, but in the long run, healthcare remains attractive.

“In the past, deals – especially for large companies – have been mainly about driving growth. Today, M&A is no longer the only means for driving growth – companies are also increasingly focused on cash flow, capitalization and portfolio management.”
Mergers and Acquisitions (M&As) have been indispensable to the medical technology industry. Next-generation and cutting-edge technologies commonly are developed by private, often single-product start-up companies, which are sold frequently to supplement the pipelines of larger, more established medtech companies. The acquirers gain technology and the entrepreneurs and investors who founded the start-up avoid the risk, cost and time of building the regulatory, legal and marketing experience to effectively commercialize the resulting products. According to Windhover, with nearly two-thirds of all medtech revenue being derived from products launched within the past two years, this model of innovation and pipeline fulfillment has been an important part of the growth of the industry.

Mergers between more mature publicly traded medtechs also have represented a large part of the M&A environment. Many large medtechs (as well as diversified conglomerates and pharmaceutical companies) have looked to acquisitions of publicly held medtech companies as a means to further diversify their portfolios and to move the needle on their top-line growth and stock prices. Several other companies (such as Hologic and Inverness Medical Innovations) have used strategic acquisitions as a vehicle to help transform themselves from Davids to mid-tier Goliaths. In addition, Private Equity (PE) houses have been significant players in the medtech M&A market over the past several years. Much of the M&A activity in recent years has been fueled by increased access to low-cost credit, overall market confidence and a “land grab” for properties within specific sectors such as nonimaging.
diagnostics, cardiovascular/vascular and orthopedics. Due to these favorable conditions, 2006 and 2007 were a record-breaking pair in the US, both for the number of deals (108 and 133, respectively) and the aggregate value of the transactions (US$80.4 billion and US$50.8 billion, respectively). In 2007, Europe witnessed 73 medtech deals for a total of US$28.0 billion.

The impact of the financial crisis

The year 2008 was well on its way to becoming another strong year for medtech M&A until the onset of the global financial crisis brought an abrupt halt to all deal activity. Through the first six months of the year, there was a total of 58 US and European deals with an aggregate value of US$31.0 billion – an average of US$534 million per deal. The three largest deals of the year occurred during this period, and the industry was within striking distance of replicating the US$62 billion spent in 2007. However, in the second half of 2008, the total transaction value (US$10.3 billion) and average dollars per deal (US$187 million) plummeted along with the rest of the global economy. With stock prices freefalling, credit markets drying up and recessionary fears clouding company outlooks, many strategic acquirers decided to hunker down and stay on the sidelines. Overall, 2008 experienced a 36.5% (178 to 113) drop in the number of deals and a 33.4% decline in total dollars (US$62 billion to US$41.3 billion) compared to 2007.

While the public markets did begin to pare back some of its losses during the first half of 2009, the general medtech M&A malaise continued during this period, as only 44 deals with an aggregate value of US$6.7 billion (average of US$153 million per deal)
were announced. More than 80% of this total figure occurred in the first quarter of 2009, including Abbott Laboratories' US$2.9 billion acquisition of ophthalmic leader Advanced Medical Optics (AMO). The Abbott/AMO deal alone constituted roughly 43% of 2009's first half M&A activity. The M&A market further declined in the second quarter of 2009 as there were only 25 deals worth US$1.4 billion (US$54 million on average) – the lowest quarterly amount since Q3 2002 when the market was still reeling from a recession caused by the burst of the dot-com bubble, the aftermath of September 11th and a series of corporate scandals. As discussed further below and in the “Deal-making in uncertain times” panel discussion on page 40, large US-based acquirers were also digesting the impact of new merger accounting rules and their potential impact on financial results and deal values.

As we entered the second half of 2009, despite the allure of significantly lower valuations of many would-be targets, larger medtech companies were placing more focus on strengthening their core businesses and enhancing operating efficiencies. The financial downturn and future market uncertainty also diminished the appetites of small- and mid-cap medtechs that are unwilling to use their depressed equity as readily to perform deals. However, as the trading multiples of certain companies decreased, some well-capitalized, forward-looking acquirers have taken advantage of lowered valuations to enter new lines of business or to enhance current product offerings. In addition, with the IPO window shut and market transformation on the horizon, some cash-strapped venture-backed companies appear more willing to reset their valuation expectations. In the near term, demand for strategic acquisitions of late-stage companies and technologies – who have removed a portion of the adoption and reimbursement risk off the table – will drive the overall deal volume within the medtech M&A market.

Analyzing the top deals

In last year’s Pulse of the industry report, we reflected upon the depth and breadth of 2007’s deal landscape. That year, 14 deals surpassed US$1 billion and 22 deals exceeded the US$500 million mark. Acquisitions were completed by a broad base of buyers, with large deals being principally consummated by diversified conglomerates and PE. In 2008, only 7 deals eclipsed the billion dollar mark and just 12 brought in more than US$500 million. Through the first half of 2009, only one deal surpassed US$1 billion dollars and just three topped US$500 million. Despite 2008 acquisitions by General Electric (of UK-based Whatman plc and New Jersey-based Vital Signs) and the Avista Capital and Nordic Capital acquisition of Bristol-Myers Squibb’s ConvaTec unit, diversified conglomerates and private equity buyers were conspicuously missing from the scene in 2008 and the first half of 2009. This 18-month period did see the return of diversified pharmaceutical acquirers in the form of Abbott, Johnson & Johnson, Novartis and Roche – they participated in four of the eight deals exceeding the billion dollar threshold.

The largest medtech deal of 2008 occurred between two Swiss corporate giants – Novartis and Nestlé. In April 2008, Novartis agreed to acquire a 25% stake in Alcon, a Swiss-based manufacturer and marketer of vision products, from Nestle for CHF 11.1 billion (US$10.5 billion). The purchase was the first half of a potential two-part deal where either company could exercise the rights to Nestlé’s remaining 52% interest in Alcon between January 2010 and July 2011, with a potential total value approaching US$39 billion. Novartis pulled the trigger on Alcon – which had sales of US$5.1 billion in 2008 – in a strategy to further diversify its business beyond pharmaceuticals. Other significant transactions which occurred in the first half of 2008 were detailed in last year’s Pulse of the industry, including the merger of Invitrogen and Applied Biosystems – now Life Technologies – in a transaction valued at US$6.7 billion, Avista Capital Partners and Nordic Capital’s acquisition of ConvaTec for US$4.1 billion, Fresenius Kabi’s acquisition of APP Pharmaceuticals for US$3.7 billion and Roche’s takeout of Ventana Medical Systems for US$3.4 billion.
### Selected US M&As

<table>
<thead>
<tr>
<th>Acquiring company</th>
<th>Location</th>
<th>Acquired company</th>
<th>Location</th>
<th>Value (US$m)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>H1 2009</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Abbott</td>
<td>Illinois</td>
<td>Advanced Medical Optics</td>
<td>Southern California</td>
<td>$2,857</td>
</tr>
<tr>
<td>Beckman Coulter</td>
<td>Southern California</td>
<td>Olympus (diagnostic systems unit)</td>
<td>Japan</td>
<td>$800</td>
</tr>
<tr>
<td>Medtronic</td>
<td>Minnesota</td>
<td>CoreValve</td>
<td>Southern California</td>
<td>$700</td>
</tr>
<tr>
<td>Covidien</td>
<td>Massachusetts</td>
<td>VNUS Medical</td>
<td>Northern California</td>
<td>$440</td>
</tr>
<tr>
<td>Medtronic</td>
<td>Minnesota</td>
<td>Ventor Technologies</td>
<td>Israel</td>
<td>$325</td>
</tr>
<tr>
<td><strong>2008</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Invitrogen</td>
<td>Southern California</td>
<td>Applied Biosystems</td>
<td>Northern California</td>
<td>$6,700</td>
</tr>
<tr>
<td>Avista Capital/</td>
<td>US/Sweden</td>
<td>ConvaTec (unit of BMS)</td>
<td>New Jersey</td>
<td>$4,100</td>
</tr>
<tr>
<td>Nordic Capital</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fresenius Kabi</td>
<td>Germany</td>
<td>APP Pharmaceuticals</td>
<td>Illinois</td>
<td>$3,700</td>
</tr>
<tr>
<td>Roche</td>
<td>Switzerland</td>
<td>Ventana Medical Systems</td>
<td>Arizona</td>
<td>$3,400</td>
</tr>
<tr>
<td>Kinetic Concepts</td>
<td>Texas</td>
<td>LifeCell</td>
<td>New Jersey</td>
<td>$1,700</td>
</tr>
<tr>
<td>Johnson &amp; Johnson</td>
<td>New Jersey</td>
<td>Mentor Corporation</td>
<td>Southern California</td>
<td>$1,073</td>
</tr>
<tr>
<td>(Ethicon)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Getinge</td>
<td>Sweden</td>
<td>Datascope</td>
<td>New Jersey</td>
<td>$865</td>
</tr>
<tr>
<td>GE Healthcare</td>
<td>Wisconsin</td>
<td>Vital Signs</td>
<td>New Jersey</td>
<td>$860</td>
</tr>
<tr>
<td>GE Healthcare</td>
<td>Wisconsin</td>
<td>Whatman plc</td>
<td>United Kingdom</td>
<td>$713</td>
</tr>
</tbody>
</table>

*Source: Ernst & Young, Capital IQ, Windhover and Jefferies & Co.*

The second half of 2008 saw a number of interesting transactions. After five months of negotiations, Johnson & Johnson’s Ethicon division completed the sale of its Professional Wound Care business (US$270 million in 2007 net sales) to PE investor One Equity Partners. Deal terms were not disclosed. J&J did not wait long to put the proceeds to work, completing two significant acquisitions prior to the end of the year. On the same day the One Equity deal closed, J&J’s Ethicon division announced its intent to acquire breast implant and aesthetic device maker Mentor Corporation for US$1.07 billion. While the cosmetic procedure market had slowed with the recession, J&J was betting that Mentor’s product lines would help the company challenge aesthetics leader Allergan and become a driver of Ethicon’s long-term growth. J&J’s Ethicon struck another deal in late December when it announced its intention to acquire Israeli biological sealant maker Omrix Biopharmaceuticals for US$438 million. J&J was eager to complete the Omrix deal prior to year end – the Mentor deal wasn’t completed until January 2009 – due to the changes in US-based business combination accounting rules that took effect for most
### Selected European M&As

<table>
<thead>
<tr>
<th>Acquiring company</th>
<th>Location</th>
<th>Acquired company</th>
<th>Location</th>
<th>Value (US$m)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>H1 2009</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medtronic</td>
<td>US</td>
<td>Ventor Technologies</td>
<td>Israel</td>
<td>$325</td>
</tr>
<tr>
<td>Inverness Medical Innovations</td>
<td>US</td>
<td>Concateno</td>
<td>UK</td>
<td>$237</td>
</tr>
<tr>
<td>Gen-Probe</td>
<td>US</td>
<td>Tepnel Life Sciences</td>
<td>UK</td>
<td>$132</td>
</tr>
<tr>
<td>Grifols</td>
<td>Spain</td>
<td>Lateral Diagnostics</td>
<td>Australia</td>
<td>$35</td>
</tr>
<tr>
<td>Thales Group</td>
<td>France</td>
<td>CMT Medical Technologies</td>
<td>Israel</td>
<td>$31</td>
</tr>
<tr>
<td><strong>2008</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Novartis</td>
<td>Switzerland</td>
<td>Alcon (25% stake)</td>
<td>Switzerland</td>
<td>$10,547</td>
</tr>
<tr>
<td>Fresenius Kabi</td>
<td>Germany</td>
<td>APP Pharmaceuticals</td>
<td>US</td>
<td>$3,700</td>
</tr>
<tr>
<td>Roche</td>
<td>Switzerland</td>
<td>Ventana Medical Systems</td>
<td>US</td>
<td>$3,400</td>
</tr>
<tr>
<td>Getinge</td>
<td>Sweden</td>
<td>Datascope</td>
<td>US</td>
<td>$865</td>
</tr>
<tr>
<td>General Electric</td>
<td>US</td>
<td>Whatman plc</td>
<td>UK</td>
<td>$713</td>
</tr>
<tr>
<td>Essilor International</td>
<td>France</td>
<td>Satisloh AG</td>
<td>Switzerland</td>
<td>$507</td>
</tr>
<tr>
<td>Johnson &amp; Johnson</td>
<td>US</td>
<td>Omrix Biopharmaceuticals</td>
<td>Israel</td>
<td>$438</td>
</tr>
<tr>
<td>(Ethicon)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bayer</td>
<td>Germany</td>
<td>Possis Medical</td>
<td>US</td>
<td>$361</td>
</tr>
<tr>
<td>St. Jude Medical</td>
<td>US</td>
<td>MediGuide</td>
<td>Israel</td>
<td>$300</td>
</tr>
<tr>
<td>St. Jude Medical</td>
<td>US</td>
<td>Radi Medical Systems</td>
<td>Sweden</td>
<td>$250</td>
</tr>
</tbody>
</table>

Source: Ernst & Young, Capital IQ, Windhover and Jefferies & Co.

Companies on 1 January 2009. These rules can significantly impact an acquirer's future earnings, financial metrics and compliance with debt covenants and were likely responsible for some of the deal activity we saw at year's end. For further insight on these new accounting rules, please see the "A closer look – New accounting rules impact M&A" (page 54). In addition to J&J, companies like St. Jude Medical and Medtronic also participated in deals before these new rules took effect. St. Jude completed its acquisition of Sweden’s Radi Medical Systems AB (a leader in physiological assessment for coronary lesions) for US$250 million on December 21 and the very next day completed a US$300 million deal for Israeli-based MediGuide, a developer of sensors for minimally invasive intrabody navigation. St. Jude’s cross-town rival Medtronic completed three 2009 deals of private, venture-backed companies prior to its April 24 year-end (and the requirement to adopt the new business combination rules on May 1), including: US$700 million for aortic valve replacement company CoreValve of Irvine, CA; US$325 million for Israeli transcatheter valve developer Ventor Technologies; and US$225 million for...
for atrial fibrillation company Ablation Frontiers of Carlsbad, CA.

Of particular interest with the CoreValve and Ventor deals was that neither of their heart valve technologies was available in the US at the time of purchase. Both of the companies had opted to launch their products in European markets due to the lengthening timelines associated with the Food and Drug Administration approval process. According to VentureSource, the US$700 million paid for CoreValve was the largest buy-out of a venture-backed medtech since 1998.

Beyond Medtronic’s moves during the first half of the year, 2009’s largest deal (thus far) was Abbott’s US$2.9 billion acquisition of Santa Ana, Calif.-based Advanced Medical Optics, a developer of cataract and laser vision-correction (LASIK) surgical products. The all-cash deal further diversified Abbott’s medtech portfolio and gave the company a leadership position in the fast-growing ophthalmic business - a new segment for Abbott. Just several months before, Abbott left the orthopedic business by selling its spine division to Stryker for US$360 million. Beckman Coulter’s purchase of the diagnostic division of Japan’s Olympus Corporation for US$800 million was the second largest deal in the first half of 2009. The acquisition gives Beckman Coulter a greater presence in Europe and Asia via Olympus’ clinical chemistry systems. The Medtronic acquisitions of CoreValve and Ventor Technologies, as well as Covidien’s US$440 million purchase of San Jose, Calif.-based VNUS Technologies, a provider of minimally invasive treatment of venous reflux, rounded out the first half of 2009’s five largest deals.

As was the case in 2007, the nonimaging diagnostic sector had the most deals (20) in 2008. However, unlike 2007, where 43.9% of all industry dollars were spent on transactions for nonimaging diagnostic businesses, only 11.6% (US$4.8 billion) of aggregate deal values were devoted to the sector, most from Roche’s acquisition of Ventana Medical Systems. After several years of a heated deal environment in nonimaging diagnostics, many of the obvious mid- to large-scale targets may have already been acquired, leading to a short-term decrease in deal values in the sector. Driven by the Invitrogen/Applied Biosystems merger, the research and other equipment category was responsible for 19.3% of all deal dollars (US$8.0 billion) in 2008, while therapeutic device multiple delivered 12.1% of dollars (US$5.0 billion) as a result of the private equity take-out of Bristol-Myers Squibb’s ConvaTec division. During the first half of 2009, two-thirds of the deals have either occurred in cardiovascular/vascular or nonimaging diagnostics, continuing a trend we have seen throughout this past decade, where these two sectors have combined for 50% of all transactions and 51% of all deal values.

Deals involving US-based medtechs

In breaking down the 2008 deals by geography, US companies were involved in more deals (79 to 58) than their European counterparts. Despite the second-half collapse, 2008 should be remembered as a strong year for M&As within the US medtech industry. While 2008’s total deal value of US$29.3 billion was significantly lower than the amounts spent in 2006 (US$80.4 billion) and 2007 (US$50.8), it was still 72% higher than the cumulative average (US$17 billion) seen between 2000 and 2005. One must remember
that 2006, and to a lesser extent 2007, witnessed several “mega-deals” of at least US$10 billion (there were three in 2006; Boston Scientific’s acquisition of Guidant for US$28.4 billion, Thermo Electron’s merger with Fisher Scientific valued at US$11.8 billion, and the private equity acquisition of Biomet for US$11.3 billion) as well as other highly leveraged transactions. In 2006 and 2007 the market also witnessed the emergence of PE funds pursuing acquisitions of medtech properties to the tune of a combined US$22.6 billion. As credit and debt markets froze in Q4 2008, PE buyers retreated.

Through the first half of 2009, there have been 28 deals for US$6.6 billion. Should this level of acquisition persist, 2009 would be the second worst year for US medtech M&As this decade after the 77 deals valued at US$7.5 billion in 2002.

An analysis of premiums paid for some of the top US deals in 2008 and the first half of 2009 shows an interesting, if not unexpected, trend began to occur in the fourth quarter of 2008. As the impact of the financial crisis took hold in Q4 2008, and the value of public medtech companies fell inline with the broader markets, some of the stated M&A premiums paid by acquirers were in reality discounts when compared to the target’s 52-week high. For example, when J&J acquired Mentor for US$31 per share, the one-day premium based on Mentor’s stock closing price the day before ($16.15 per share) was 92%. However, when the US$31 purchase price is compared to Mentor’s 52-week high of US$40.01, J&J actually paid a 23% discount – a gap of 115 basis points. Several other deals in the fourth quarter of 2008 and the first half of 2009 saw similar valuation gaps. In contrast, through the first three quarters of 2008, the majority of valuation gaps were within 10% and only a couple of deals were completed as discounts off of the 52-week high.

**Deals involving European-based medtechs**

In 2008, the number of deals involving European companies and total deal values were down 20.5% and 18.6%, respectively, from their 2007 levels. Overall, Europe had 58 transactions totaling US$22.8 billion for an average of US$393.3 million per deal. Only 28% of the total occurred in the second half of 2008 and the freefall in deal activity continued into 2009. Through the first six months of 2009, only 18 deals totaling US$862 million (US$47.9 million per deal) occurred in all of Europe.

The continent was home to the largest transaction of 2008 – the CHF 11.1 billion (US$10.5 billion) deal for a 25% in stake Alcon between Nestlé and Novartis – and five of the top 10 deals in 2008 were consummated by European businesses. With Novartis and Roche pulling the trigger on two the year’s three largest deals, 65% of all transactions measured by value were completed by pharmaceutical companies.

**A retreat of PE?**

According to McKinsey, 4% of all global acquisitions involved capital from PE in 2000. By 2007, that number had ballooned to 20%. During that period, PE firms were raising hundreds of billions of dollars each year, and by 2007, the global buyout industry had approximately US$900 billion under management. Larger equity funds, combined with readily available debt financing, sparked unprecedented deal volume by these firms across all industries during this period – including medtech.
While certain PEs like Warburg Pincus had been involved with the organic development of medtech companies, PE as a whole wasn’t particularly interested in making large acquisitions within the industry. From 2000 to 2005, 14 private equity deals were completed for a combined US$2.9 billion, an average of US$207 million per deal. During that six-year stretch, the largest deal was completed in 2003 by New York City-based Welsh, Carson, Anderson & Stowe, a US$650 million buyout of nonimaging diagnostic company AmeriPath. Welsh Carson subsequently sold AmeriPath to Quest Diagnostics in 2007 for US$2 billion. From 2006 to 2008, 19 PE deals were completed for a combined US$27 billion, an average of just over US$1.4 billion per deal. The announcement of the US$11.4 billion “club deal” (the consortium also included The Blackstone Group, Goldman Sachs Capital Partners, Kohlberg Kravis Roberts & Co. and TPG) to acquire Biomet was significant news in 2006. After the Biomet deal, more PE dollars came into medtech over the next two years and PE houses became a key part of the M&A boom in the industry. In 2007, US$9.8 billion worth of acquisitions occurred, with three of the deals going for at least US$1 billion, including Warburg Pincus’ acquisition of Bausch & Lomb for US$4.5 billion; Onex Healthcare Holdings’ purchase of Eastman Kodak Healthcare, now called Carestream Health for US$2.6 billion; and ReAble Therapeutics’ (The Blackstone Group) acquisition of DJ Orthopedics for US$1.6 billion. In 2008, this figure dropped to US$4.4 billion – almost entirely through the Avista Capital Partners’ and Nordic Capital’s acquisition of Bristol-Myer Squibb’s ConvaTec unit for US$4.1 billion.

Since the second half of 2008, only two PE acquisitions with announced terms have closed, with a value of only US$31 million. Private equity houses are retrenching and evaluating new strategies such as minority investments (i.e., One Equity Partners and ArthroCare). With the era of easy credit over, expect to see deal values in the range of US$500 to US$750 million. Even at these deals sizes, private equity will likely have to invest more in equity than seen in the past and therefore will be more selective with a focus on underperforming assets or neglected divisions within larger companies. In fact, several major PE houses have established experienced management teams to evaluate carve-out transactions from companies looking to shed noncore or underperforming assets. Still others will seek to buy down debt at discounted rates on existing portfolio investments, essentially enhancing their returns. Finally, firms will be looking at recent IPO classes. As discussed earlier, many of these companies are suffering from

**US M&A premiums by date – 2008 and first half of 2009**

![Graph showing M&A premiums by date](image_url)

*Source: Ernst & Young, Capital IQ, Windhover and Jefferies & Co. Chart shows deals with values in excess of US$150 million*
### US transactions by segment – 2008 and the first half of 2009

<table>
<thead>
<tr>
<th>Segment</th>
<th>Number of deals</th>
<th>Value (US$m)</th>
<th>% of total US$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nonimaging diagnostics</td>
<td>26</td>
<td>$6,408</td>
<td>17.9%</td>
</tr>
<tr>
<td>Research and other equipment</td>
<td>12</td>
<td>$8,005</td>
<td>22.3%</td>
</tr>
<tr>
<td>Therapeutic devices (all)</td>
<td>58</td>
<td>$16,942</td>
<td>47.2%</td>
</tr>
<tr>
<td>Cardiovascular/vascular</td>
<td>17</td>
<td>$3,721</td>
<td>10.4%</td>
</tr>
<tr>
<td>Orthopedic</td>
<td>7</td>
<td>$650</td>
<td>1.8%</td>
</tr>
<tr>
<td>Wound care</td>
<td>6</td>
<td>$2,241</td>
<td>6.2%</td>
</tr>
<tr>
<td>Aesthetics</td>
<td>5</td>
<td>$1,499</td>
<td>4.2%</td>
</tr>
<tr>
<td>Neurology</td>
<td>6</td>
<td>$353</td>
<td>1.0%</td>
</tr>
<tr>
<td>Multiple</td>
<td>4</td>
<td>$5,038</td>
<td>14.0%</td>
</tr>
<tr>
<td>All others</td>
<td>13</td>
<td>$3,440</td>
<td>9.6%</td>
</tr>
<tr>
<td>Other</td>
<td>9</td>
<td>$4,486</td>
<td>12.5%</td>
</tr>
<tr>
<td>Imaging</td>
<td>2</td>
<td>$49</td>
<td>0.1%</td>
</tr>
</tbody>
</table>

Source: Ernst & Young, Capital IQ, Jefferies & Company and Windhover.

### European transactions by segment – 2008 and the first half of 2009

<table>
<thead>
<tr>
<th>Segment</th>
<th>Number of deals</th>
<th>Value (€ m)</th>
<th>% of total €</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other</td>
<td>21</td>
<td>€3,657</td>
<td>22.1%</td>
</tr>
<tr>
<td>Nonimaging diagnostics</td>
<td>16</td>
<td>€2,759</td>
<td>16.7%</td>
</tr>
<tr>
<td>Research and other equipment</td>
<td>10</td>
<td>€659</td>
<td>4.0%</td>
</tr>
<tr>
<td>Therapeutic devices (all)</td>
<td>25</td>
<td>€8,985</td>
<td>54.3%</td>
</tr>
<tr>
<td>Oncology</td>
<td>5</td>
<td>€96</td>
<td>0.6%</td>
</tr>
<tr>
<td>Cardiovascular/vascular</td>
<td>5</td>
<td>€1,209</td>
<td>7.3%</td>
</tr>
<tr>
<td>Wound care</td>
<td>3</td>
<td>€353</td>
<td>2.1%</td>
</tr>
<tr>
<td>Ophthalmic</td>
<td>2</td>
<td>€7,172</td>
<td>43.3%</td>
</tr>
<tr>
<td>All others</td>
<td>10</td>
<td>€146</td>
<td>1.0%</td>
</tr>
<tr>
<td>Imaging</td>
<td>4</td>
<td>€62</td>
<td>0.4%</td>
</tr>
</tbody>
</table>

Source: Ernst & Young, Capital IQ, Jefferies & Company and Windhover.
Mergers and acquisitions are a constant in the medtech industry, and often gaps in valuation expectations tend to spur creative deal structures. Earn-out payments or other contingent considerations have been commonly used in this regard, especially when the target is closely held. Several recent transactions involving publicly traded companies in the biotechnology sector have also embraced contingent payments as a mechanism to get deals done rapidly. Will this trend spread to the medical technology sector?

While companies negotiating a deal may be most focused on strategic and valuation issues, creative transaction structures with contingent payments such as earn-outs can carry significant accounting consequences. These implications should be fully explored before signing a deal, particularly in light of the 2009 adoption of US Financial Accounting Standards Board Statement No. 141(R), Business Combinations, which is substantially consistent with International Accounting Standard 3(R). Under these rules, acquirers need to consider the fair value of contingent payments and record these amounts as liabilities at the date of the acquisition.

New accounting rules impact M&A

Mergers and acquisitions are a constant in the medtech industry, and often gaps in valuation expectations tend to spur creative deal structures. Earn-out payments or other contingent considerations have been commonly used in this regard, especially when the target is closely held. Several recent transactions involving publicly traded companies in the biotechnology sector have also embraced contingent payments as a mechanism to get deals done rapidly. Will this trend spread to the medical technology sector?

While companies negotiating a deal may be most focused on strategic and valuation issues, creative transaction structures with contingent payments such as earn-outs can carry significant accounting consequences. These implications should be fully explored before signing a deal, particularly in light of the 2009 adoption of US Financial Accounting Standards Board Statement No. 141(R), Business Combinations, which is substantially consistent with International Accounting Standard 3(R). Under these rules, acquirers need to consider the fair value of contingent payments and record these amounts as liabilities at the date of the acquisition.

Statement 141(R) and the comparable international standard also require that the fair value of purchased in-process R&D be recorded as an asset on the date of the acquisition and then evaluated for impairment over time. If a product is ultimately commercialized, the asset would be amortized to expense over the expected life of the product. Judgments around impairment will be inherently subjective and will typically require consultation with valuation specialists. Further, under US standards, transactions where a company provides an up-front payment with an option to purchase the entire company at a later date for a predetermined price may require the acquirer to consolidate the operations of the target. Interestingly, under Statement 141(R), if the target is consolidated and subsequently the milestone is achieved, the contingent consideration paid is recorded in stockholders’ equity and does not require the revaluation of any assets of the target – including in-process R&D.

These new rules, while complicated and at times subjective, will not overshadow the business rationale for transactions. Management teams will be charged with explaining in a clear and transparent manner the applicable accounting treatment, and financial statement users, including analysts, will need to adapt to a new world in which significant adjustments to purchased assets and liabilities in subsequent periods will be increasingly common.
In this report, medical technology (medtech) companies are defined as public 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, prerevenue 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.
- **Nonimaging diagnostics:** companies developing products used to diagnose or monitor conditions via nonimaging 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 are kept separate from those of the nonconglomerates. 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
- Cardinal Health (now CareFusion)
- Danaher: Medical Technologies
- GE Healthcare
- Genzyme: Diagnostics & Ortho
- Hospira: Medication Management Systems and other devices
- Johnson & Johnson Medical Devices & Diagnostics
- Kimberly-Clark Health Care
- Pall Life Sciences
- Teleflex Medical

#### Europe
- Agfa-Gevaert
- Alcon (Nestlé/Novartis)
- Beiersdorf: Hansaplast
- Carl Zeiss Meditec
- Draeger Medical
- Philips Healthcare
- Roche Diagnostics
- Siemens Healthcare
- Smiths Medical
Acknowledgements

Project leadership

Gautam Jaggi and Glen Giovannetti 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 content was clear, concise and comprehensive. Gautam also encapsulated the spirit and themes of this report by writing the introduction article.

John Babitt provided strategic vision for this project and brought his years of experience to the identification and analysis of industry trends. John was instrumental in conducting interviews for the two roundtable articles, and was also responsible for editing the financing and transactions articles and writing "A closer look – New accounting rules impact M&A."

As the project manager and lead author for *Pulse of the industry*, Jason Hillenbach had responsibility for the entire content and quality of this publication. He was also responsible for the collection and analysis of all US data and European M&A data and was the researcher and writer of the financial, financing and transaction articles. Jason was also the editor of the two roundtable articles.

Strategic direction

Special thanks to Siegfried Bialojan, Kevin Casey, Heinrich Christen, Dave Copley, Dan Kleeburg, Kim Letch, Bill Miller, Scott Morrison and Richard Ramko, who all played a key role in the development of this report. Their invaluable insights and firsthand experience helped define the report’s key themes and focus.

Data analysis

Nina Hahn led and managed the data collection and analysis for the European section of the report. Her tireless efforts enabled us to broaden its scope beyond the United States in this year’s edition.

Eric Duhaime was invaluable in all aspects of the report – from data collection and analysis to research and strategic insight.

David Tigay collected financial data, while Amir Hakakha, Kim Medland and Michael Spencer helped with the fact checking and quality review of data throughout the publication.

Writing and editing assistance

Numerous contributors helped draft and write articles throughout *Pulse of the industry*. Debra McReavy used her firsthand knowledge of the US hospital marketplace to write “US hospitals under pressure,” while Edi Dahinden composed initial drafts of the European sections of the financing and transactions articles. The “closer look” articles were drafted by several individuals, including Melanie Trinidad (on the Sunshine Act), Bruce Bouchard and Ron Xavier (on government incentives) and Yoram Wilamowski (on the Israeli industry).

Russell Colton and Scott Chapski brought their incomparable skills as copy editors to this publication. Their patience, hard work and attention to detail were unparalleled. Lisa Pease applied her proofreading expertise throughout the report.

Design

This publication would not look the way it does without the diligence and creativity of John Fogarty, who managed and implemented 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 collaborated on this publication as well.
Data exhibit index

Medical technology at a glance – 2008 3
The year in financing – 2008 (US$m) 4
The year in transactions – 2008 (US$m) 5
What a difference a year makes 12
US market capitalization 13
European market capitalization 13
US public and VC-backed private companies by segment – 2008 16
European public and VC-backed private companies by segment – 2008 16
Leading US states by number of medtech companies 17
Leading European countries by number of medtech companies 17
US revenue growth by product group, 2007–2008 19
Top US revenue growth leaders in 2008 21
Selected US revenue trends by segment – H1 2009 vs. H1 2008 21
Percentage declines in US market capitalization – 31 December 2007 to 30 June 2009 22
Going, going, gone? 23
Haves and have-nots 23
European revenue growth by product group 24
European revenue growth by disease category – therapeutic devices, 2007-2008 24
Top European revenue growth leaders in 2008 25
US financing 28
European financing 28
US financing by quarter 29

(Continued next page)
European financing by quarter

Capital raised in 2008 and the first half of 2009 by leading US regions

Capital raised in 2008 and the first half of 2009 by leading European countries

US venture capital

European venture capital

Top 10 US venture rounds of 2008 and the first half of 2009

Top 10 European venture rounds of 2008 and the first half of 2009

The path to an initial public offering – US

Mass exodus – 16 US IPOs withdrawn since 2008


European IPO performance – Classes of 2007 and 2008

US mergers and acquisitions

European M&As

Selected US M&As

Selected European M&As

US M&As by type of buyer

European M&As by type of buyer

US M&A premiums by date – 2008 and first half of 2009

US transactions by segment – 2008 and the first half of 2009

European transactions by segment – 2008 and the first half of 2009

US exchange rate
(US dollars per per national currency)

<table>
<thead>
<tr>
<th></th>
<th>H1 2009</th>
<th>2008</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Euro zone</td>
<td>.7075</td>
<td>.6799</td>
<td>.7297</td>
</tr>
<tr>
<td>Sweden</td>
<td>n/a</td>
<td>.1289</td>
<td>n/a</td>
</tr>
<tr>
<td>Switzerland</td>
<td>n/a</td>
<td>.9459</td>
<td>n/a</td>
</tr>
<tr>
<td>Location</td>
<td>Name</td>
<td>Email</td>
<td>Phone</td>
</tr>
<tr>
<td>---------------------------</td>
<td>-----------------------</td>
<td>-------------------------------</td>
<td>----------------</td>
</tr>
<tr>
<td>New York/New Jersey</td>
<td>Carolyn Buck Luce</td>
<td><a href="mailto:carolyn.buck-luce@ey.com">carolyn.buck-luce@ey.com</a></td>
<td>+1 212 773 6450</td>
</tr>
<tr>
<td>Boston</td>
<td>Glen Giovannetti</td>
<td><a href="mailto:glen.giovannetti@ey.com">glen.giovannetti@ey.com</a></td>
<td>+1 617 585 1998</td>
</tr>
<tr>
<td>Boston</td>
<td>Connie Austin</td>
<td><a href="mailto:connie.austin@ey.com">connie.austin@ey.com</a></td>
<td>+1 617 585 1912</td>
</tr>
<tr>
<td>Zurich</td>
<td>Patrick Flochel</td>
<td><a href="mailto:patrick.flochel@ch.ey.com">patrick.flochel@ch.ey.com</a></td>
<td>+41 58 286 4148</td>
</tr>
<tr>
<td>Boston</td>
<td>Jason Hillenbach</td>
<td><a href="mailto:jason.hillenbach@ey.com">jason.hillenbach@ey.com</a></td>
<td>+1 617 375 1244</td>
</tr>
<tr>
<td>Philadelphia</td>
<td>Mark Hassenplug</td>
<td><a href="mailto:mark.hassenplug@ey.com">mark.hassenplug@ey.com</a></td>
<td>+1 215 448 5127</td>
</tr>
<tr>
<td>Boston</td>
<td>Scott Sarazen</td>
<td><a href="mailto:scott.sarazen@ey.com">scott.sarazen@ey.com</a></td>
<td>+1 617 585 3524</td>
</tr>
<tr>
<td>Belgium</td>
<td>Brussels</td>
<td>Thomas Sileghem</td>
<td>+32 2 774 9536</td>
</tr>
<tr>
<td>Denmark</td>
<td>Copenhagen</td>
<td>Benny Lyne Sørensen</td>
<td>+45 358 72525</td>
</tr>
<tr>
<td>France</td>
<td>Paris</td>
<td>Pascale Augé</td>
<td>+33 1 46 93 77 23</td>
</tr>
<tr>
<td>Belgium</td>
<td>Mannheim</td>
<td>Siegfried Blajojan</td>
<td>+49 621 4208 11405</td>
</tr>
<tr>
<td>Israel</td>
<td>Tel Aviv</td>
<td>Yoram Wilamowski</td>
<td>+972 362 32519</td>
</tr>
<tr>
<td>Italy</td>
<td>Milan</td>
<td>Lapo Ercoli</td>
<td>+39 02 7221 2546</td>
</tr>
<tr>
<td>Netherlands</td>
<td>Amsterdam</td>
<td>Jules Verhagen</td>
<td>+31 88 40 71888</td>
</tr>
<tr>
<td>Denmark</td>
<td>Copenhagen</td>
<td>Benny Lyne Sørensen</td>
<td>+45 358 72525</td>
</tr>
<tr>
<td>Switzerland</td>
<td>Zurich</td>
<td>Heinrich Christen</td>
<td>+41 58 286 3485</td>
</tr>
<tr>
<td>Switzerland</td>
<td>Basel</td>
<td>Jürg Zürcher</td>
<td>+41 58 286 84 03</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>London</td>
<td>Les Clifford</td>
<td>+44 20 7951 8600</td>
</tr>
<tr>
<td>United States</td>
<td>Boston</td>
<td>Andrew Vrigian</td>
<td>+1 617 585 1975</td>
</tr>
<tr>
<td>United States</td>
<td>Kevin Casey</td>
<td><a href="mailto:kevin.casey1@ey.com">kevin.casey1@ey.com</a></td>
<td>+1 617 585 1817</td>
</tr>
<tr>
<td>United States</td>
<td>Michael Donovan</td>
<td><a href="mailto:michael.donovan@ey.com">michael.donovan@ey.com</a></td>
<td>+1 617 585 1957</td>
</tr>
<tr>
<td>United States</td>
<td>Joseph Bruno</td>
<td><a href="mailto:joseph.bruno@ey.com">joseph.bruno@ey.com</a></td>
<td>+1 617 585 1944</td>
</tr>
<tr>
<td>United States</td>
<td>Philadelphia</td>
<td>Steve Simpson</td>
<td>+1 215 448 5309</td>
</tr>
<tr>
<td>United States</td>
<td>Amy Dorfmeister</td>
<td><a href="mailto:amy.dorfmeister@ey.com">amy.dorfmeister@ey.com</a></td>
<td>+1 215 448 5550</td>
</tr>
<tr>
<td>United States</td>
<td>Minneapolis</td>
<td>Bill Miller</td>
<td>+1 612 371 6984</td>
</tr>
<tr>
<td>United States</td>
<td>Stephen Stenbeck</td>
<td><a href="mailto:stephen.stenbeck@ey.com">stephen.stenbeck@ey.com</a></td>
<td>+1 612 371 6994</td>
</tr>
<tr>
<td>United States</td>
<td>Ajay Gupta</td>
<td><a href="mailto:ajay.gupta@ey.com">ajay.gupta@ey.com</a></td>
<td>+1 612 371 8325</td>
</tr>
<tr>
<td>New York/New Jersey</td>
<td>John Babitt</td>
<td><a href="mailto:john.babitt@ey.com">john.babitt@ey.com</a></td>
<td>+1 212 773 0912</td>
</tr>
<tr>
<td>United States</td>
<td>Dave DeMarco</td>
<td><a href="mailto:dave.demarco@ey.com">dave.demarco@ey.com</a></td>
<td>+1 732 516 4602</td>
</tr>
<tr>
<td>North Carolina</td>
<td>Michael Constantino</td>
<td><a href="mailto:michael.constantino@ey.com">michael.constantino@ey.com</a></td>
<td>+1 919 981 2802</td>
</tr>
<tr>
<td>Orange County</td>
<td>Dave Copley</td>
<td><a href="mailto:david.copley@ey.com">david.copley@ey.com</a></td>
<td>+1 949 437 0250</td>
</tr>
<tr>
<td>Orange County</td>
<td>Kim Letch</td>
<td><a href="mailto:kim.letch@ey.com">kim.letch@ey.com</a></td>
<td>+1 949 437 0244</td>
</tr>
<tr>
<td>San Diego</td>
<td>Dan Kieburg</td>
<td><a href="mailto:daniel.kieburg@ey.com">daniel.kieburg@ey.com</a></td>
<td>+1 858 535 7209</td>
</tr>
<tr>
<td>San Francisco Bay Area</td>
<td>Chris Nolet</td>
<td><a href="mailto:chris.nole@ey.com">chris.nole@ey.com</a></td>
<td>+1 650 496 1620</td>
</tr>
<tr>
<td>Texas</td>
<td>Carole Faig</td>
<td><a href="mailto:carole.faig@ey.com">carole.faig@ey.com</a></td>
<td>+1 713 750 1535</td>
</tr>
</tbody>
</table>
About Ernst & Young
Ernst & Young is a global leader in assurance, tax, transaction and advisory services. Worldwide, our 135,000 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.

For more information, please visit www.ey.com.

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. Ernst & Young LLP is a client-serving member firm of Ernst & Young Global and of Ernst & Young Americas operating in the US.

www.ey.com/medtech

© 2009 EYGM Limited.
All Rights Reserved.

EYG No. FN0001

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

This publication contains information in summary form and is therefore intended for general guidance only. It is not intended to be a substitute for detailed research or the exercise of professional judgment. Neither Ernst & Young LLP nor any other member of the global Ernst & Young organization can accept any responsibility for loss occasioned to any person acting or refraining from action as a result of any material in this publication. On any specific matter, reference should be made to the appropriate advisor.