

Resistant in any recession?

US medtech financial update and outlook

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At the end of September 2008, when Ernst & Young released its inaugural report on the US medical technology sector, the industry's aggregate market capitalization was up roughly 3% for the year, compared to 20% for the S&P 500. Deal-making activity for the first six months was largely on pace with the record-breaking levels seen in 2006 and 2007. Venture capital appeared poised for another strong year.

To put it mildly, the world has changed a lot since then. The stock market has fallen steeply amid patterns of dizzying volatility, governments across the world have taken unprecedented measures to shore up their economies and financial institutions, and the crisis has spread swiftly across industries and geographies.

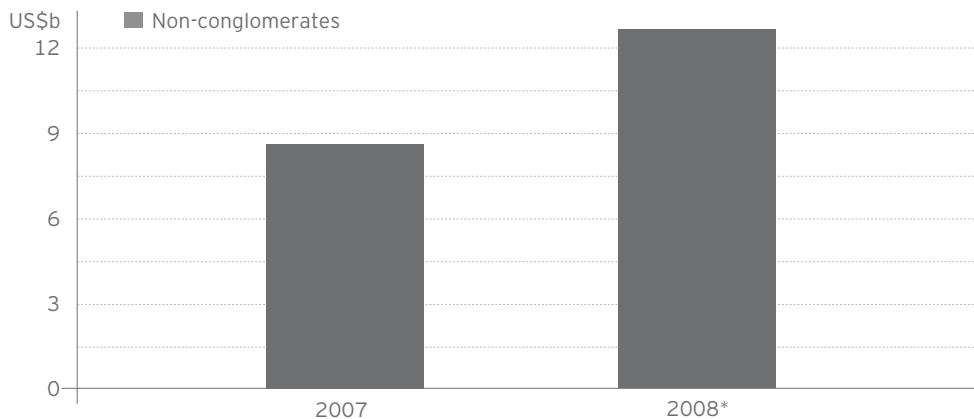
How has medtech held up in all of this? Given the unprecedented developments in the global economy, we have produced this update to our industry report to give our clients and friends an understanding of the rapidly changing market conditions as well as insights into what companies should focus on as they navigate these rough waters.

2008 industry revenues are on pace to grow by 7% ...



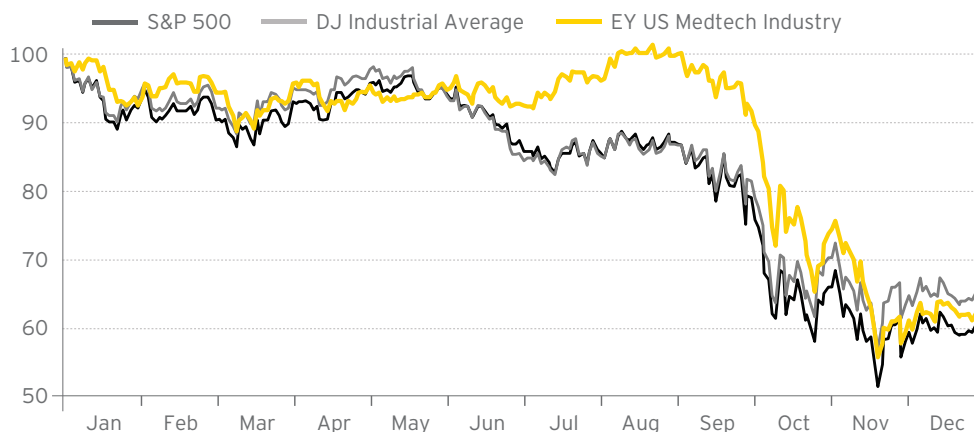
Source: Ernst & Young and company filings
* Data is extrapolated for the entire year using figures from Q1-Q3 2008

... and net income of non-conglomerates is on pace to grow by 46% ...



Source: Ernst & Young and company filings
* Data is extrapolated for the entire year using figures from Q1-Q3 2008

... but company valuations plummeted in the fourth quarter.



Source: Ernst & Young and FactSet Research

Financial performance

During the first nine months of 2008, medtech revenues of US publicly traded companies reached US\$145.1 billion – a pace that, if sustained, would surpass the industry’s 2007 annual total of US\$180 billion by 7.2% and exceed the 4.5% growth seen in 2007. As in 2007, thirteen large conglomerates – including companies such as Johnson & Johnson, GE Healthcare and Baxter International – accounted for over a third of the industry’s revenues. However, while the conglomerates were on pace to grow revenue by a modest 2.2% in 2008, non-conglomerates were projected to increase revenue by a robust 10.3%. Particularly noteworthy are several mid-cap companies such as Hologic, Inverness Medical Innovations, ev3 and Greatbatch, which have experienced impressive top-line growth through a series of recent acquisitions.

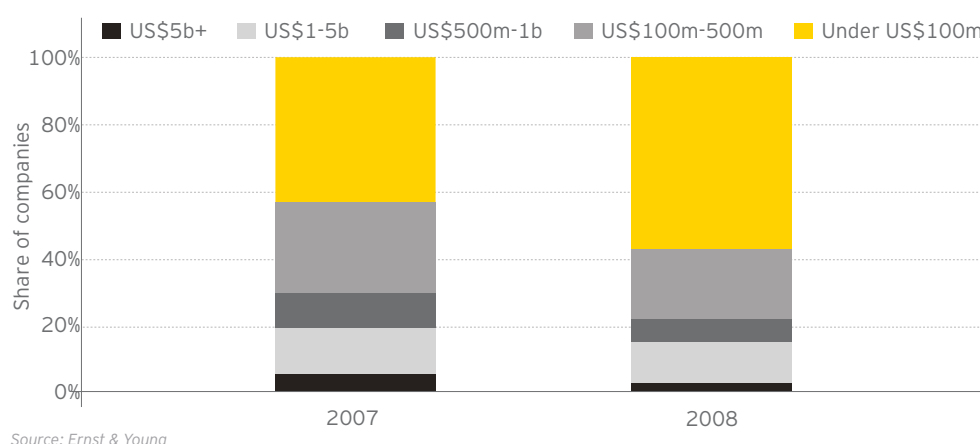
While medtech stocks have often been a relatively safe haven for investors, they were hit hard in 2008. The sector remained fairly steady through the first three quarters – as of 30 September, the industry’s aggregate market capitalization (excluding conglomerates) was down only 4% relative to the beginning of the year. In the fourth quarter, however, medtech stocks followed the overall market in a sharply downward direction. By the end of 2008, the sector’s market cap had fallen 36% relative to the beginning of the year – essentially performing no better than aggregate market indices such as the Dow Jones Industrial Average (down 34%), the S&P 500 (down 39%) and the NASDAQ Composite (down 41%). While dozens of industry stalwarts saw their market valuations decline by billions of dollars, a number of small- and mid-cap medtech companies experienced significant increases in market valuation,

driven largely by strong sales growth and successes on the product-development front. Examples include Sequenom (which achieved significant milestones in the development of its proprietary Down syndrome test), Thoratec (which successfully launched and adopted its HeartMate II device), Luminex (led by strong sales of its xMAP(R) system) and Edwards Lifesciences (which saw strong sales growth of core products).

The year 2009 will bring more challenges for numerous medtech companies. Many hospitals and healthcare providers, which are generally the most significant purchasers of medical devices and supplies, are experiencing or projecting declines in admissions. As unemployment climbs, hospitals are also beginning to see increases in uninsured patients, and therefore a rise in bad-debt expense. The increase in unemployment and the uninsured-patient base is occurring at a time when many government programs are seeing declining tax revenues. The uninsured are less likely to visit physicians for routine medical care, which can result in increased treatment costs at a later date, further driving up uncompensated care and bad-debt expense.

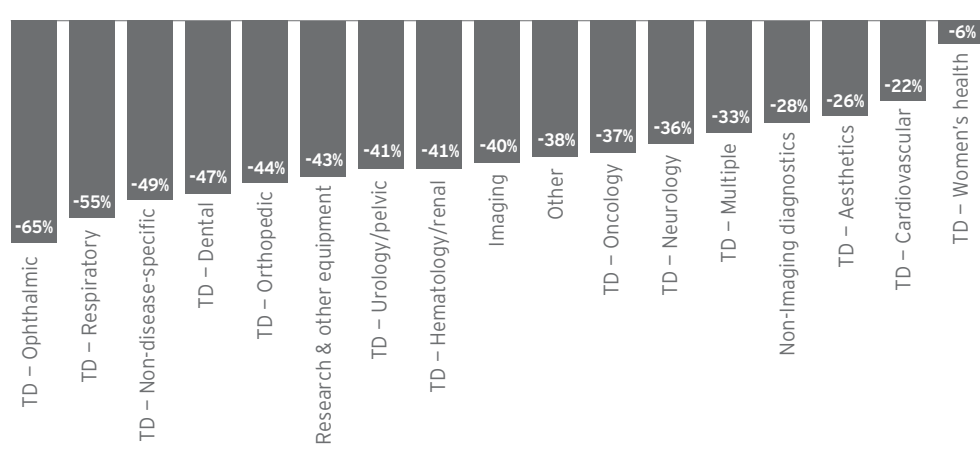
Providers have also seen significant declines in elective and cosmetic surgeries, which has a differential impact on individual industry segments. For instance, patients have been delaying orthopedic procedures such as knee and hip replacements and disk-related back surgeries, as well as cosmetic procedures such as augmentations, bariatric and lasik procedures – often some of a provider’s most profitable procedures. Conversely, devices and supplies for procedures with a higher degree of medical necessity, such as pacemakers, stents and oncology procedures, are less likely to be impacted. In addition, hospitals can expect a decline in returns from investment portfolios which

The market capitalization of small and large companies fell ...



Source: Ernst & Young

... but the impact differed across segments.



Source: Ernst & Young

TD=Therapeutic devices

they often rely upon to make up for operating shortfalls and uncompensated care.

Given these trends, we can expect to see cost-reduction measures by hospitals and other healthcare providers, with a corresponding impact on many medtech companies. Companies selling big-ticket equipment may see expansion and replacement orders decline as providers seek to extend the useful life of existing technology. Medtech companies may also need to defend their supplier relationships as hospitals move to consolidate vendors and seek volume or other discounts.

Vendors may be asked for significant discounts and other concessions that could make it challenging for smaller manufacturers and suppliers to keep pace with the rebates and discounts offered by larger medical device companies. During the fourth quarter of 2008, two public companies fell victim to the economic downturn. CHAD Therapeutics, a developer of sleep disorder products, and San Diego-based Artes Medical, a maker of dermal fillers for cosmetic treatments, both filed for Chapter 7 bankruptcy and liquidated their assets.

Capital formation

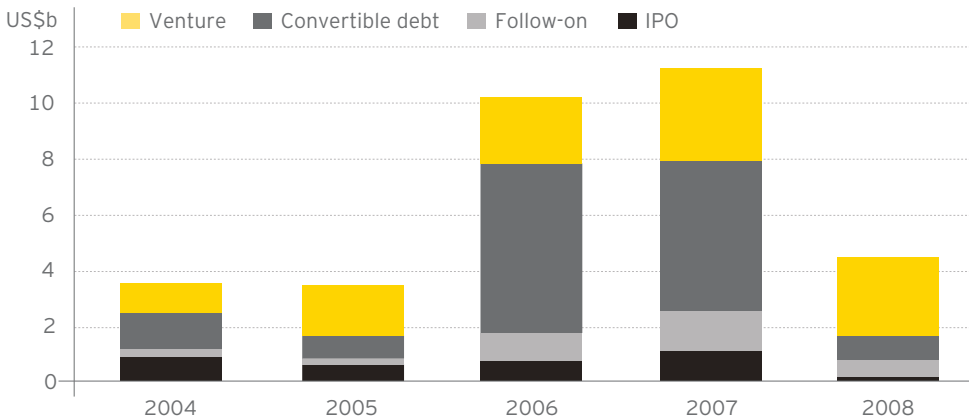
With the financial crisis taking its toll on the global public markets, 2008 was a tumultuous year for capital formation in the US medtech industry. In 2008, total US financing reached US\$4.6 billion – a 59% decline compared to 2007. However, it is important to note that both 2006 and 2007 were record years for financing, and the 2008 total still surpasses the average amounts raised from 2000-2005.

The record levels achieved in 2006 and 2007 were principally driven by large debt offerings to either finance strategic acquisitions or to buy back common stock. In the wake of the financial crisis, it is not surprising to see that the collapse in debt financing has had such a negative impact on medtech's overall financing amounts.

Although there was a decent amount of IPO activity in the first quarter of 2008 with CardioNet, MAKO Surgical and Lifeline Scientific going public and raising a total of US\$115 million, there have been no IPOs since then, and at least nine companies have pulled planned offerings. The public markets are expected to remain closed for the foreseeable future, with most analysts not expecting additional IPOs until the end of 2009 or later. Furthermore, the follow-on public market has been hit hard in 2008 – funding was 53% lower in 2008 than the US\$1.5 billion raised in 2007.

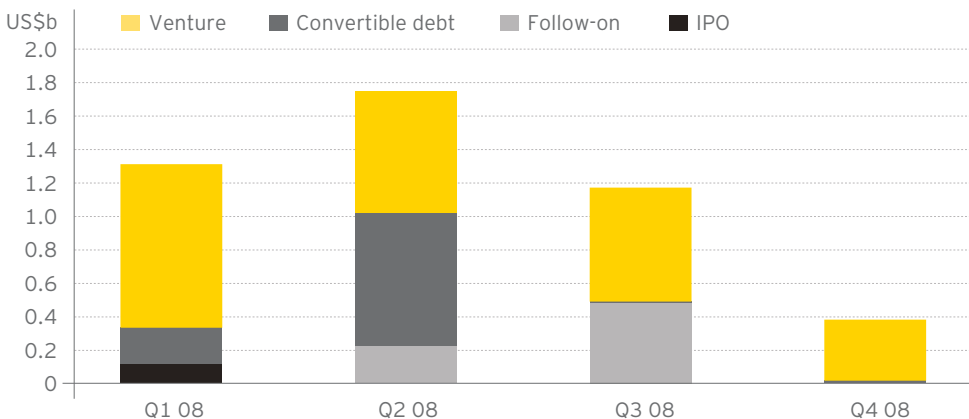
The one area of investment that remained somewhat resilient for much of the year is venture capital (VC), where the industry raised US\$2.8 billion during 2008. While this total is down by 18% compared to the year prior, 2007 itself was a record year for VC financing. The relative resilience in this segment is attributable to a couple of factors. First, since the traditional exit for medtech venture investments has predominantly come through acquisitions, and since strategic buyers continue to pursue emerging medtech companies, the dearth of IPO exits has less of an

While venture capital held up, total financing was down sharply ...



Source: Ernst & Young, ThinkEquity, Windhover, Dow Jones VentureSource and Jefferies & Co.

... with most of the decline occurring in the fourth quarter.



Source: Ernst & Young, ThinkEquity, Windhover, Dow Jones VentureSource and Jefferies & Co.

impact on medtech investments than on investments in industries such as biotechnology. Second, medtech's shorter (and less expensive) innovation cycles have historically led to quicker exits than in biotech, giving VCs a greater degree of comfort in the current market.

However, as with market capitalization, the story on the financing front changed dramatically later in the year. Out of the US\$4.6 billion in total medtech financing in 2008, only US\$380 million occurred in the fourth quarter. And while the sector raised over US\$1 billion in the first half of the year through debt offerings, it raised a paltry US\$16 million in the second half, after the credit crisis started to deepen.

The year's three IPOs (down from 13 in each of the two preceding years) occurred in the first quarter and netted companies much less on average than the IPO proceeds in 2006 and 2007. As the global recession continues to deepen, these are potentially worrying trends, particularly for smaller companies.

Mergers and acquisitions

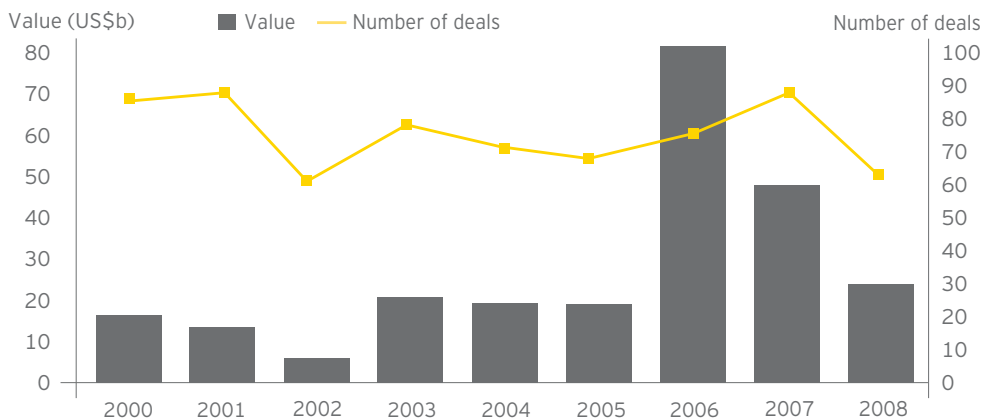
As with other financial measures, merger and acquisition activity was considerably stronger early in the year than in later months. During the first six months of 2008, the US medtech industry saw US\$19 billion in M&A transactions – roughly on par with the pace during the first half of 2007. However, as easy access to capital dried up and stock markets plunged, only US\$5 billion in deal activity occurred during the second half of the year. Consequently, M&A activity for the entire year fell 49%, from US\$48.5 billion in 2007 to US\$24.9 billion in 2008. In addition, there has been a decline in the number of deals – from 87 in 2007 to 63 in 2008 – and a decline in average deal size.

A significant share of M&A activity in the medtech sector has historically consisted of acquisitions of emerging private firms by large public companies – the industry’s “feeder mechanism” for innovative new technologies. Over the last couple of years, this has been supplemented by mergers of publicly traded medtechs for significant amounts, including many for considerations in excess of a billion dollars. Megadeals such as Boston Scientific/ Guidant and Thermo Electron/Fisher Scientific in 2006 created large upswings in total deal values.

In 2008, these big mergers between public companies largely disappeared, resulting in a decline in total deal values – there were only five transactions of US\$1 billion or more completed last year, down from 12 such deals in 2007. Still, the total M&A value and average deal size in 2008 easily surpassed the levels seen during the 2000-2005 period, prior to the recent boom in megadeal activity.

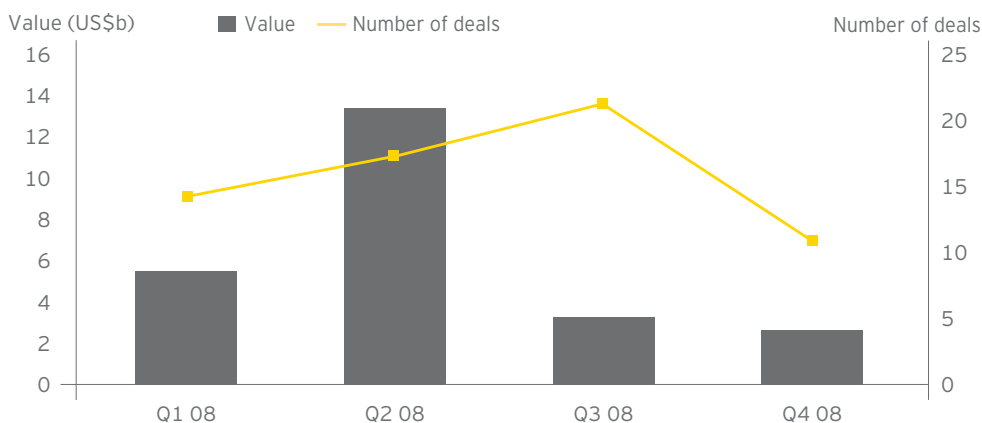
While conglomerate and private equity buyers accounted for two-thirds of 2007 deals with values over US\$1 billion, these firms have taken more of a hands-off approach in 2008. In their place, we

2008 M&A activity fell to pre-2006 levels ...



Source: Ernst & Young

... with most of the decline in the second half of the year.



Source: Ernst & Young

continue to see more pure-play medtech companies, such as Invitrogen, Kinetic Concepts, Hologic and Medtronic, driving deal activity. Today’s transactions are smaller, strategic medtech-medtech deals that fit into a buyer’s core operations.

The decline in deal values may stem in part from the heated deal activity of the last couple of years and the natural cyclical nature of large-scale public M&As. After the boom of big-dollar deals in recent years, today’s medtech industry is much more concentrated than it was just three years ago. Many of the obvious targets may have already been acquired, and some buyers may simply be pausing to integrate their acquired assets. In addition, the increased

cost of borrowing and decline in credit availability have made financing large acquisitions more challenging.

To some extent, the decline in the latter half of the year may also be a result of the advent of lower valuations. As the market caps of smaller companies have declined, some prospective buyers may be waiting for asset prices to fall even further before initiating acquisitions. This would suggest that deal flow should pick up in 2009 – albeit at substantially lower valuations. In the long run, of course, the medtech business model is dependent on M&As, and the sector will need a high volume of deals to sustain innovation and company formation.

Weathering the storm

The financial barometers discussed above reveal a remarkably consistent story. From market capitalization to funding patterns to mergers and acquisitions, medtech indicators have changed dramatically, starting in late 2008. These changes raise a couple of compelling questions. How are medtech companies operating in this challenging climate? And what can firms do to survive the storm?

The global financial crisis is creating new risks and challenges across geographies and sectors, and medtech is no exception. In this section, we group these challenges into six broad categories.

Raising capital

Given that most medtech firms are small-cap public companies or venture-backed entities engaged in capital-intensive R&D, it is no surprise that raising capital has become a paramount challenge in today's capital markets. In this new environment, firms need to start by examining any existing plans for capital-market activities – refinancings, capital raising, debt repayments, lender negotiations – and evaluate how these have been impacted in the current environment. Relationships with investors are more important than ever, and firms should prioritize communications with VCs and institutional investors, including through nondeal roadshows.

As traditional sources of funding dry up, companies also need to explore alternative sources of capital. This could include examining whether their existing platforms and projects could be made eligible for government grants, incentive programs and/or disease-foundation funding. Creative financing structures such as royalty financing and project-finance deals have been increasingly visible in the biotech industry in recent years, and some medtechs may be

able to position themselves for these funding structures. Lastly, in an environment where IPOs have all but disappeared, companies looking to go public may also want to be on the lookout for reverse-merger candidates, or be open to the prospect of being a strategic transaction.

Managing capital and cash burn

Raising capital is only half the picture; in the current environment, it is every bit as important to deploy capital efficiently. Indeed, as many companies find it harder to raise funds for their operations, they are increasingly focused on managing capital and cash burn. Immediate belt-tightening measures such as reviewing expense policies and supplier relationships and drawing on available commitments can help, as can headcount reductions through hiring freezes and layoffs.

Beyond these steps, however, companies need to take a more comprehensive view of their cash flow forecasting and working-capital management. This should include evaluating how their current capital structures match their business strategies, as well as assessing current levels of working-capital flexibility and understanding how these could change under downside scenarios. Based on this evaluation, firms will need to take steps to manage cash more tightly and improve cash flow forecasting.

This will often include restructuring measures and new operating plans. Many firms may need to focus their R&D efforts on high-potential product opportunities and sell nonessential assets or programs. Companies will restructure operations to better leverage low-cost markets and contract service providers. And in extreme cases where such measures are unsuccessful, companies may need to start exploring hibernation and/or bankruptcy-protection scenarios.

Managing debt

Since the onset of the global financial crisis – which was, it should be remembered, precipitated by a credit crunch – managing debt has become increasingly important for medtech companies. Firms need to take stock of how much debt they have on their books and who owns it. As lenders become increasingly stringent, firms need to build transparent communications with debt providers and rating agencies to maintain their access to credit. They should make compliance with debt covenants and repayment terms a high priority and should proactively renegotiate terms whenever necessary.

Managing risk

If there is one common theme that underlies the current turmoil in the global economy, it is risk. The global financial crisis is creating new risks for firms while exacerbating or compounding existing challenges. (For additional information, see *The 2009 Ernst & Young business risk report: the top 10 risks for life sciences companies*, being released in early 2009.) In this environment, companies of all sizes need to make risk management a priority and need to approach the issue holistically. This process should start with a comprehensive enterprise-wide risk assessment to ensure that all key risks are being covered. Senior management needs to set the tone with a clear articulation of risk appetite and measurement, and boards and management need to be full participants in evaluating risk/reward trade-offs.

As part of the risk-management process, companies may need to consider corporate-governance changes as part of this process, including tightening internal controls, impairment testing, and evaluating the frequency of board meetings or credit crunch special projects team meetings. As many firms look to restructure their operations, they will need to consider the impact of

restructurings on their internal controls and control environments.

Given the systemic nature of the current crisis, counterparty risk has acquired greater significance. Medtech companies should evaluate counterparty risk with regard to their lenders, customers and key suppliers. This could include a review of supply chain and third-party relationships for vulnerability and "fit." As many firms increase their reliance on third parties to contain costs and tap efficiencies, they will still need to ensure regulatory compliance in an environment of changing regulatory regimes and increased enforcement.

Human capital

In an industry driven by innovation and intellectual property, human assets remain some of the most valuable resources of medtech companies. In the current environment, companies are challenged to strike a fine balance between reducing payroll costs, retaining valuable employees and even expanding headcount in focused, strategic ways. As the value of equity-based compensation declines and layoffs become inevitable for many firms, the challenge will be to maintain morale with remaining employees, and management should proactively communicate with workers about their actions and strategies. Since stock-based compensation is a key component of employee incentives in the medtech industry, companies will need to evaluate these programs in light of recent stock performance to retain key talent. And as competitors initiate layoffs, merge or cease operations, companies may be able to selectively and strategically take advantage of the talent pool newly available in the market.

Seizing opportunities

Tremendous change inevitably creates new risks, but these risks also create new opportunities, and firms should also remain vigilant about identifying and seizing on

opportunities whenever possible. In the current economic climate, firms need to monitor competitors' strengths and weaknesses. For example, larger, better-capitalized companies may have pricing leverage over smaller competitors. Another area where size differences could play out is deals. For large firms, the fall in market valuations creates opportunities to acquire strategic assets at attractive prices. Meanwhile, an increasing number of smaller companies may start looking at combinations with other similarly sized entities to acquire scale, mitigate risk and improve efficiencies.

Outlook

While 2008 started strong for the medtech industry, conditions have taken a marked turn for the worse. The global financial crisis continues to intensify and there is no expectation of a rapid turnaround. While

most medical technologies are considered fairly recession-resistant, firms should anticipate significant challenges in a global recession that is still deepening and likely to be prolonged.

Firms will need to find alternative ways to raise capital and manage existing capital more efficiently. In the current economic climate, managing risk, debt and human capital have become more important as well. As they face increasing scrutiny from payors, providers and potential acquirors, companies will need to think about positioning their offerings in ways that offer genuine advances in medical outcomes while helping to reduce overall healthcare costs. Companies that bring creativity, focus and discipline to these challenges will have an easier time receiving funding, attracting acquisition suitors and prospering in the market, even in a daunting credit environment. ►

Ten questions to ask yourself in the current economic climate

1. How will our business be impacted by the current credit crunch? What risk/opportunity assessments have we conducted and what are the conclusions and actions items?
2. How does the current capital structure match our business strategy?
3. How much debt and how many debt-like items do we have, and who owns the debt?
4. What plans are in place for capital-market activities – refinancings, capital raisings, debt repayments, lender negotiations – and how have these been impacted?
5. Who is, or might be, at risk in my customer base or supply chain?
6. What steps are we taking to manage cash more tightly and improve cash flow forecasting?
7. How much working-capital flexibility is there in our business and how does this change under downside scenarios?
8. What communication strategies are in place for debt providers, equity analysts and rating agencies?
9. What plans do we have for seizing opportunities to grow our business through acquisition, sales growth and earnings improvement?
10. What corporate-governance changes are envisioned – internal controls, impairment testing, frequency meetings? How will any restructurings affect our internal controls and control environment?

Source: Ernst & Young

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You can contact the Global Biotechnology Center at +1 617 585 1800, or by email at globalbiotechcenter@ey.com.

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