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MEDICAL DEVICES REPORT

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Economic Recovery, But Not For Medical Devices

THOMAS P. KOUCHOUKOS returned to Stifel Nicolaus in August 2008 as a Medical Technology Analyst, focusing primarily on the women's health, urology, peripheral vascular, neurovascular and biomaterials market sectors. Prior to joining Stifel Nicolaus, Mr. Kouchoukos was a Vice President and Senior Analyst covering the medical technology sector at Northland Securities, Inc. From 2005 to 2007, he was a Senior Medical Technology Analyst with A.G. Edwards & Sons, and from 2003 to 2005 he served as Vice President and Senior Equity Analyst for Stifel, Nicolaus & Company, following companies in the medical technology sector. Mr. Kouchoukos is a CFA charterholder and member of the CFA Institute and the St. Louis Society of Financial Analysts. He received his Bachelor of Science from Vanderbilt University and his MBA from the Olin School of Business at Washington University in St. Louis.

GREG SIMPSON joined Stifel Nicolaus in July 2003 to cover the medical technology sector. Prior to joining the firm, he spent 15 years at A. G. Edwards as a Vice President and Senior Medical Device Analyst. Mr. Simpson graduated from St. Louis University with degrees in both accounting and finance, and he has an MBA from the University of Missouri. He is a member of the St. Louis Society of Financial Analysts and is a CFA charterholder. Mr. Simpson was ranked first among earnings estimators and second among stock pickers in the health care equipment and supplies industry by the Forbes/StarMine survey in 2007.

SECTOR — MEDICAL DEVICES

(ABF401) TWST: What is your assessment of the medical devices sector, given the recent passage of the health care bill?

Mr. Simpson: It has obviously been an interesting year or so. Reform has clearly been an overhang on the group for much of this time. We saw some better performance out of the group when it looked like health care reform was not going to pass, and then the prospects for reform changed on a dime a couple of months ago and reform looked likely once again. It didn't seem to have as much effect as I think many investors had largely tuned it out by that point. The reality after it passed, and we knew what it encompassed, there were two initial reactions — you had a modest rally in the overall group, literally a day or so, and then I think people came to the conclusion that the reality is that reform doesn't mean much for the medical device sector in the short term, as most of the impact starts to kick in a few years down the road. Needless to say, a lot can change between now and then. Maybe more importantly from the medical device perspective, there's a lot of things taking place in the market right now, some are related to health care reform, some separate and unrelated to health care reform. These industry trends, in our opinion, will put growing pressures on this market regardless of the health care reform bill. Are there any positives associated with reform for the medical device group? I think you get a very minor positive for some of the device companies as a result of more patients ultimately coming into the market. It affects some sectors within med tech more than others, obviously, but the reality is that the vast majority of the uninsured people in this country are of younger age and well below the key age groups for most of the companies focused on implantable devices, such as orthopedics, cardiac rhythm management or heart valves. The notion that these uninsured entering the market is some sort of major boon for the device manufacturers is a fallacy for the most part, in our opinion. On the other hand, the medical device tax is obviously a negative for the industry and can't be anything but be negative in its impact on innovation. Companies will find a way to deal with it, but with the other pressures we were seeing kind of slow within the market — especially on the pricing front — companies are going to find places to cut back, and we do think it will ultimately impair

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innovation going forward. So to summarize, yes, I would say reform is generally a negative for the group. But again, most of the impact is a few years away and I think investors will worry about this on another day. From my own perspective, I don't think we fixed anything as far as the health care system is concerned; I don't think we have bent the proverbial cost curve, and that's an issue. I think we basically put off problems for another day. In the meantime, I don't think passing reform changes any of the things we're seeing within the marketplace in terms of what hospital administrators or hospitals are doing, how doctors are being negatively affected. I think we will continue to see incremental pricing pressure in the medical device sector. And in some of the key product categories where we have seen a lack of new product flow, lack of innovation, we are moving towards commodity-like status. That raises some red flags for us on a longer-term basis, as do the seemingly accelerating trends toward vendor consolidation and direct physician employment in areas like orthopedics and cardiovascular. We specifically think direct physician employment is a trend to watch, especially in orthopedics, as it can shift pricing power increasingly to the hospitals and away from the implant manufacturers.

TWST: How do you think this sector has been affected by the economy? Do you think the prospects in the context of the economy have improved?

Mr. Simpson: Yes, I think so. I feel modestly more positive about the economy, and I have been pretty negative up to this point. That's good and bad for medical device stocks though. An improving economy and growing signs of recovery could have a somewhat positive effect on sectors like orthopedics, which could get a boost if the unemployment picture begins to improve. But we haven't seen that to this point. That is a sector within medical devices that was thought to be economically insensitive in the past but has proven to have a greater degree of economic sensitivity than previously suspected. On the other hand, if you look at the flow of dollars and how portfolio managers tend to play sector rotations, health care stocks in general and medical device stocks in particular tend to do better in the early stages of a recession and then underperform coming out of recession, and we're in the early stages of an expansion. If you look at the group, it has underperformed in recent weeks and it's underperformed the S&P on a year-to-date basis as well. While I think the belief is out there that most funds have tended to be underinvested in health care, reality is the more investors become convinced that the economy is improving and we're in a legitimate expansion, you could actually see dollars potentially flow out of health care names.

Highlights

Stifel Analysts Thomas Kouchoukos and Greg Simpson both view the medical devices space as a mixed bag. While the recovering economy could have a positive effect on some sectors, such as orthopedics, both analysts signal that medical device stocks tend to underperform coming out of a recession. Mr. Kouchoukos says he is not expecting meaningful fundamental improvement, although he does offer his favorite medical device names. Mr. Simpson outlines those med tech stocks that most worry him, while highlighting others that may have game-changing technology. Both analysts also discuss women's health and cardiac assist companies, as well as M&A. Companies include: Hologic (HOLX); ev3 (EVVV); Micrus Endovascular (MEND); C.R. Bard (BCR); Covidien (COV); Medtronic (MDT); Inverness Medical Innovations (IMA); Abiomed (ABMD); ATS Medical (ATSI); The Spectranetics Corporation (SPNC); Edwards Lifesciences (EW); Thoratec (THOR); Zimmer Holdings (ZMH); Stryker (SYK); Boston Scientific (BSX) and Conceptus (CPTS).

Mr. Kouchoukos: Yes, I would say in terms of the recession, and procedure volumes and hospital spending, I think it's been somewhat mixed for our companies across sectors. Greg already touched on the orthopedic impact, which has been noticeable. For a company like **Hologic** (HOLX), which is a leading producer of digital mammography systems for breast cancer screening and diagnosis, that's an area where we really saw hospital spending fall off a cliff at the beginning of recession. And to be frank about it, we really haven't seen that come back yet. I think there is a lot of hope on Wall Street that we will see stabilization in hospital capital spending in the back half of 2010, but I do not think investors are necessarily looking for any real growth this year. So we have seen the capital equipment side of the business, for a lot of these companies, really take a hit through the recession, and that's something that at this point, while we have easier comps throughout this year, we are not really expecting to see meaningful fundamental improvement. In terms of procedure volumes, in the groups that I cover — peripheral vascular, neurovascular, women's health — the impact has been somewhat mixed. For neurovascular procedures, when we're talking about treating hemorrhagic stroke, a patient will likely receive treatment no matter what the economy is doing. So this market segment has held up quite well, and we have seen very nice growth from companies such as **ev3** (EVVV) and **Micrus Endovascular** (MEND) in the past year.

In the surgical markets, where companies like **C.R. Bard** (BCR) and **Covidien** (COV) focus on general surgery, bariatrics and hernia repair, we really haven't seen a big difference in procedural volumes. The final area for me would be women's health and urology, where it may be that some of these procedures are deferrable, whether it'd be a lifestyle-type procedure, such as treating stress incontinence or pelvic prolapse. In these cases, a woman can theoretically put the procedure off until she just can't take it anymore. That said, however, we have seen procedural growth hold up fairly well in the areas of permanent contraception and on the male side in treating incontinence and erectile dysfunction. So it really has been a mixed bag.

I think one thing that we have seen with respect to the economy, and Greg touched on this a bit earlier, is our belief that hospitals are taking some of the power away from the industry in the pricing scheme. I think the recession has reset the bar in that hospitals during the depths of the recession said, "Listen, you have to work with us to get pricing lower." And I think as we come out of the recession, it might be tougher to reverse that trend going forward.

TWST: What about your top stock picks at the moment? What companies do you like and why?

Mr. Kouchoukos: The names that we like by cap — in the large-cap arena, I like **Covidien**, a diversified health care company that has undergone a number of dramatic changes since spinning from **Tyco** in 2007. While the company plays in the pharmaceutical and medical supply sectors of the market, most of the positive change to this point has been led by the higher-margin medical devices business, which represents approximately 60% of sales and is the company's fastest-growing business segment. The stock performed quite well in 2009, and we believe that factors such as the potential for further margin expansion, P&L leverage, continued performance in medical devices and the impact of a replenished pharmaceutical pipeline can drive share valuation higher in 2010 and beyond.

Simpson: Are there any positives associated with reform for the medical device group? I think you get a very minor positive for some of the device companies as a result of more patients ultimately coming into the market.

1-Year Daily Chart of Covidien

Chart provided by www.BigCharts.com

Greg recommends **Medtronic** (MDT) as more of a total return vehicle, but one in the very early stages of an attractive new product cycle. Mid cap, I think our best idea at this time would probably be **Inverness Medical** (IMA), a dominant player in rapid point-of-care diagnostics and the company that could benefit nicely from health care reform, given its focus on more effective and efficient management of patients with chronic conditions. On the small side, Greg likes **Abiomed** (ABMD) and the potential of its Impella product line; **ATS Medical** (ATSI), for its increasingly attractive tissue valve product line and its attractiveness as a potential acquisition candidate, while I like **Spectranetics** (SPNC), a company that produces medical lasers for the treatment of peripheral artery disease (PAD) and cardiac lead removal. The company recently launched a new product called TurboTandem that should expand its addressable market opportunity in the PAD market, and a combination of solid clinical data and increasing market awareness is driving impressive growth rates in the cardiac lead removal side of the business. Given our expectation for **Spectranetics** to reach sustainable profitability in mid-2010 and our opinion that shares are attractively valued, we think small-cap investors should be paying attention to this name. In addition to our "buy"-rated companies, there are some other names that we like very much that we are not currently recommending due to valuation, and we could talk about those as well.

TWST: What would those be?

Mr. Kouchoukos: For me it would be, **Micrus Endovascular**, which I believe is one of the highest-quality small-cap names in the medical device space. In our view, there are many exciting potential catalysts that are shaping up for fiscal 2010 and 2011, including a new product cycle, the potential to expand into new high-growth geographies, forthcoming clinical data that could validate the superiority of the company's Cerecyte technology and the prospect of continued operating margin expansion.

TWST: Are there any companies that you have a "sell" on, or that you are less confident about at the moment?

Mr. Kouchoukos: In my group, there are really not. I probably should have said on the positive side, there are two I think Greg is excited about in terms of areas of medical technology that he thinks are very promising. One would be percutaneous valve technology, the other one would be ventricular assist devices. Top players in these segments are **Edwards Lifesciences** (EW) and **Thoratec** (THOR). Greg can touch on those; not currently recommending them, but Greg can tell you why.

Mr. Simpson: There are some names that I'm watching that if they got a little more expensive, I'd be a bit concerned about. If you look at the overall group valuation, the medical device and med supply groups are trading right in line with the S&P 500. Historically speaking, in the last 20 years or so, the average multiple has traded on average at greater than a 20% premium to the S&P 500. So some of the pushback we get is that the group is cheap. We feel a little differently. The growth rates in this industry for many of the large-cap companies have slowed and in many cases have come down pretty dramatically. So I don't think we will see this group trade at that same premium valuation going forward. So many of the larger-cap names have rebounded to the point where they are pretty fully valued. That includes a couple of the orthopedic names like **Zimmer** (ZMH) and **Stryker** (SYK) — wonderful companies, but growth rates have changed; the orthopedic market has gotten a little tougher, pricing is more difficult. If we see the valuations increase from where we are at

Kouchoukos: I think one thing that we have seen with respect to the economy, and Greg touched on this a bit earlier, is our belief that hospitals are taking some of the power away from industry in the pricing scheme.

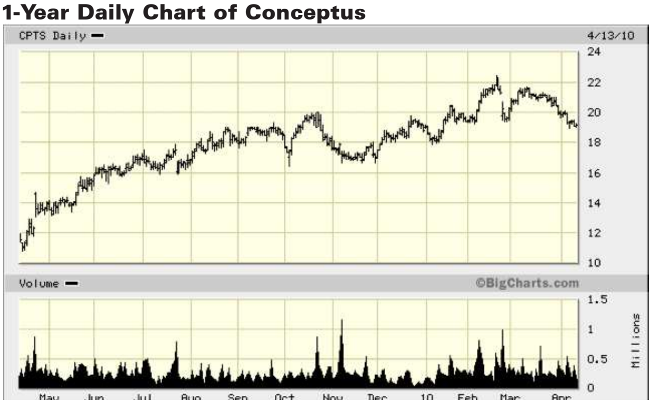
currently, I'd be increasingly negative on the prospects, even though they are extremely well-run companies.

TWST: Are there any companies in particular whose products address unmet market needs and therefore may rapidly affect their growth?

Mr. Simpson: Yes, Tom just mentioned actually two of the names — **Edwards Lifesciences**, with transcatheter valves, and **Thoratec**, which is the leading player in ventricular assist devices, specifically for the destination therapy indication. Both of those are exciting and significant product opportunities. Both those companies are the leaders in those areas and with nice head starts over the competition. We are not recommending either of them currently, but that's a valuation decision. Both of those market opportunities represent underserved markets, unmet needs and new growth opportunities. With respect to **Edwards**, many people think transcatheter valves offer an alternative or replacement for traditional valve replacement and the reality is not the case. Transcatheter valves open up the market to new patients, patients that traditionally have not been eligible for surgery or are considered very high risk. That could be at least a-couple-of-billion-dollars opportunity and obviously as a result, several companies are certainly chasing hard after that market. **Edwards** is in a very, very strong position and will have at least a two year or longer head start over **Medtronic** in the U.S. market.

Kouchoukos: One product in the women's heath space that has been out since 2002 but which is still very exciting is the Essure device from Conceptus. The Essure procedure is a minimally invasive alternative to tubal ligation for permanent contraception.

1-Year Daily Chart of Conceptus



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Cardiac assist is another area that has been gaining fans but is still a lesser-known opportunity. This market has been a long-time incoming — the whole cardiac assist market and destination therapy indication had been a disappointment for years, and it has taken a long time to get to the point where you have the right devices that are good enough from a clinical perspective to develop this market. There is certainly no shortage of potential patients, given the limited number of transplant hearts available. Like transcatheter valves, this could also be a multibillion-dollar market opportunity.

Simpson: From a historical perspective, the group still looks cheap. But we don't think growth rates are necessarily relevant, given that growth rates have come down, especially with the majority of the larger cap names in the group.

In addition, looking at another area the of cardiac assist sector, but a little different than what **Thoratec** is doing, **Abiomed**, one of our recommended small-cap names, has a catheter-based assist device that is primarily used in the cath lab for acute heart failure. That's a unique device, a very exciting device. They have done reasonably well with it since the product received FDA approval, and this is another product area where we think the opportunity is potentially very significant. **Abiomed** is the kind of company, and this is the kind of device, that I think will garner acquisition interest from some of the larger companies down the road. In fact, I think this is an ideal acquisition for a company like **Boston Scientific** (BSX), which has a significant cath lab presence and is clearly in need of new growth drivers.

Mr. Kouchoukos: One product in the women's heath space that has been out since 2002 but which is still very exciting is the Essure device from **Conceptus** (CPTS). The Essure procedure is a minimally invasive alternative to tubal ligation for permanent contraception. In the early days, Essure was somewhat of a missionary sell for **Conceptus**, since the procedure represented a pretty radical change in practice for OB/GYNs who tend to be relatively conservative. Since this time, **Conceptus** has done a remarkable job of getting the product out there in the market, obtaining widespread reimbursement for the product and more recently using direct-to-consumer advertising as a means to build consumer awareness for the device. The company's growth trajectory has been quite strong over the past several years, and it just posted about 30% top-line growth in 2009. While the year-over-year growth comparisons are becoming a bit more challenging, **Conceptus** appears to have a lot of momentum remaining in its business. I think what's interesting is there has been a lot of debate in the marketplace about a second player coming to the market, which is **Hologic**'s Adiana product. It's a device that does not appear to stack up to Essure from a clinical perspective, but which is backed by a pretty powerful women's health franchise and which we believe will at least find its own niche in the market. While we would expect to see some near-term market disruption as **Hologic** launches Adiana on a full commercial scale, we think **Conceptus** should benefit over the long term since having a second player should further boost awareness for the procedure and further validates this procedure within the physician mindset. So I would say in the women's health space, this seems to be one of the more exciting technologies out in the marketplace.

TWST: As you talk to management, what is their level of confidence at the moment?

Mr. Kouchoukos: I think we are seeing management much more confident today than they were, say, a year ago, when everything looked like it was falling apart. That said, I still think management teams are cautious. When we talk to companies with capital equipment components to their revenue stream, management still seems very cautious. But I'd say they are optimistic that the worst is behind them. Looking to a year back, when we spoke with management teams who had their stocks cut in half and there was virtually no visibility into the health of the broader economy, many were not sure which way things were going to go. Everyone was pretty spooked and management teams pulled expectations back pretty dramatically for the coming year. During this time, we saw a lot of companies hunker down, get their costs in order and shore up their P&Ls in anticipation of a tough couple of years. As the year progressed, however, we saw many companies outperform these lowered expectations and the market obviously liked this dynamic. I think with the small-cap names, at least in my group — I think this has happened with Greg's as well — the recession actually brought some religion to some of these management teams in terms of costs and how they allocate capital. For example, **Micrus Endovascular** is one that I cover that had a tough quarter at the height of the recession in the February-March 2009 time frame. Management made a commitment to achieve sustainable profitability by cutting expenses and realizing efficiencies, and **Micrus** has been profitable in each of the past four quarters. This was obviously attractive to investors, as we saw the stock work last year and continue to work into this year. So for me, talking to our management teams today, I think the bottom line is that there is still a lot of uncertainty out there with respect to many variables, including the economy, health care reform and the prospect of a more challenging FDA process. But I think they are keeping their heads up and feel good about their respective businesses.

Kouchoukos: I think there is a lot of hope on Wall Street that we will see stabilization in hospital capital spending in the back half of 2010, but I do not think investors are necessarily looking for any real growth this year.

Mr. Simpson: I think it's all relative in the sense that a year or so ago, in late 2008, early 2009, the environment was about as bad as it could have been, and medical devices is not a sector where you really expect that. The way the economy just kind of fell apart, the swiftness in the declines of high-quality, "blue-chip" stocks that were thought to be safe, defensive investments really left a lot of people, including company managements, pretty shell shocked. There was so much uncertainty out there and you could literally hear the stress coming through on conference calls. Health care has usually been a safe haven, and it was anything but during that period. The good news, I think, is that many of these management teams emerged from this period stronger for the experience. In addition, the good companies, as Tom said, tightened their belts and I think they probably emerge as better companies as a result. Looking forward, while the economy looks better and many of the stocks have recovered, it's still a very tough environment for medical device companies.

Simpson: FDA reform is something to keep an eye on going forward and is a likely catalyst for the heightened acquisition activity that we expect.

TWST: What has investor confidence been like lately?

Mr. Simpson: Again, it's all relative to some extent, but it's clear that investor confidence has improved. While there is still a lot of uncertainty, a rising market and improving stock prices really helps investors overcome the fears of a year ago. I suppose that's human nature and something of a recurring cycle in the way the market works. Still, I think most investors remember quite vividly the dark days of late 2008/early 2009 and emerged a bit more cautious as a result.

1-Year Daily Chart of Micrus Endovascular

Chart provided by www.BigCharts.com

TWST: Not necessarily a bad thing, right?

Mr. Simpson: No, that's true. As the market works higher though, greed frequently overtakes common sense. And given some of the trends we are watching in the industry that concern us longer term, valuations clearly bear watching. And again, the economy is still kind of a mixed bag as far as I am concerned. But even I will acknowledge that I am somewhat incrementally more upbeat on the economy than I was, say, three months ago.

TWST: What are you advising investors to do, given your take on the economy and the health care situation?

Mr. Simpson: We still think investors need to be somewhat cautious in the stock pickers' environment going forward. There are certainly cross currents to consider. For example, from a historical perspective, the group still looks cheap. But we don't think growth rates are necessarily relevant, given that growth rates have come down, especially with the majority of the larger-cap names in the group. In addition, there are undeniable pricing pressures in several of the key product categories, including stents, CRM and orthopedics. So we think there are reasons why the group is cheap. As a result, we think more so than ever, stock selection becomes more important than it has been in the past. Another issue to look for going forward, we continue to expect acquisition activity will pick up going forward, and that we'll increasingly see the large companies become more active and aggressive in buying up some of the smaller companies in the sector, possibly to the extent that we saw in the late 1990s.

TWST: Tom, is there anything you would like to add?

Mr. Kouchoukos: Yes, I agree with Greg. To go back to your investor question, we have seen a pickup in calls and inquiries about the potential for a pickup in M&A, who the acquirers would be and who the possible targets may be. Certainly, I think for a lot of these companies, **Conceptus** is one that has kind of borne the brunt of getting FDA approval, getting reimbursement; they've proven their business model, and I think they are a viable M&A candidate. As a pure-play, high-growth and profitable neurovascular company, **Micrus Endovascular** is another one that has received a lot of chatter about a possible takeout down the road. I think this one would also fit well within the portfolio of a larger company. And then to the acquirer side, like Greg said, with growth rates coming down for many of these large companies who are flush with cash, I think it makes good sense that they will be buyers. I cover **Covidien**, which has been very active in their M&A process, and we've seen them do several deals since they were spun from **Tyco**. It's been part of their growth strategy, and I think they will continue to put capital to work and continue to buy companies going forward.

Mr. Simpson: The one thing we didn't touch on, and it actually fits real well with what we were just talking about, is the prospect for FDA reform. That is one of the catalysts that we think will help fuel increased M&A activity. As the FDA approval process gets tougher, longer and more costly, we believe that small companies with already approved products become more valuable to the bigger players. At the same time, a tougher FDA process will add greater uncertainty for smaller companies, which could make these companies more willing sellers going forward. So FDA reform is something to keep an eye on going forward and is a likely catalyst for the heightened acquisition activity that we expect.

TWST: Thank you. (MRR)

Note: Opinions and recommendations are as of 04/06/2010.

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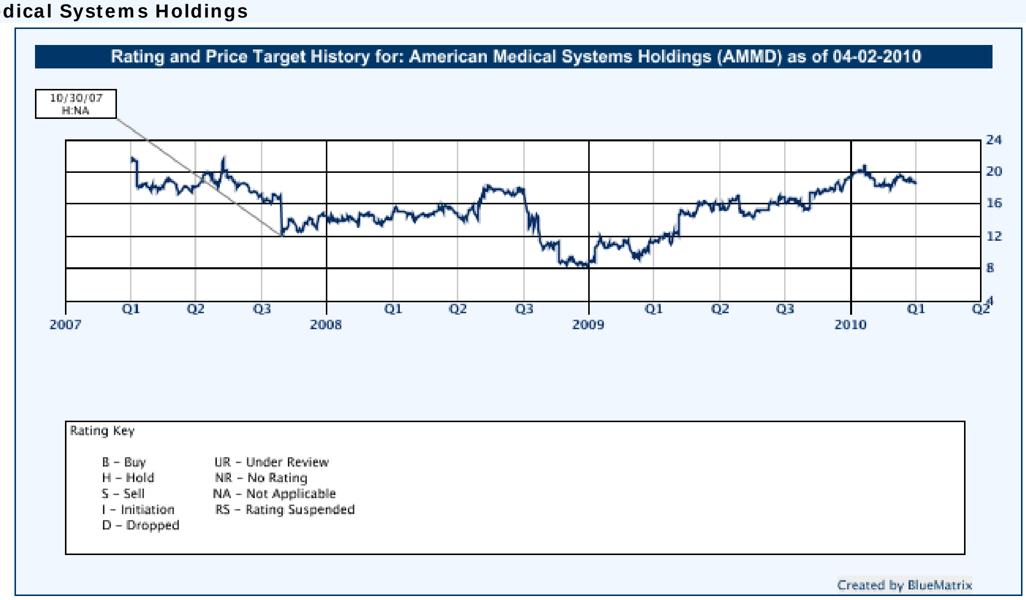

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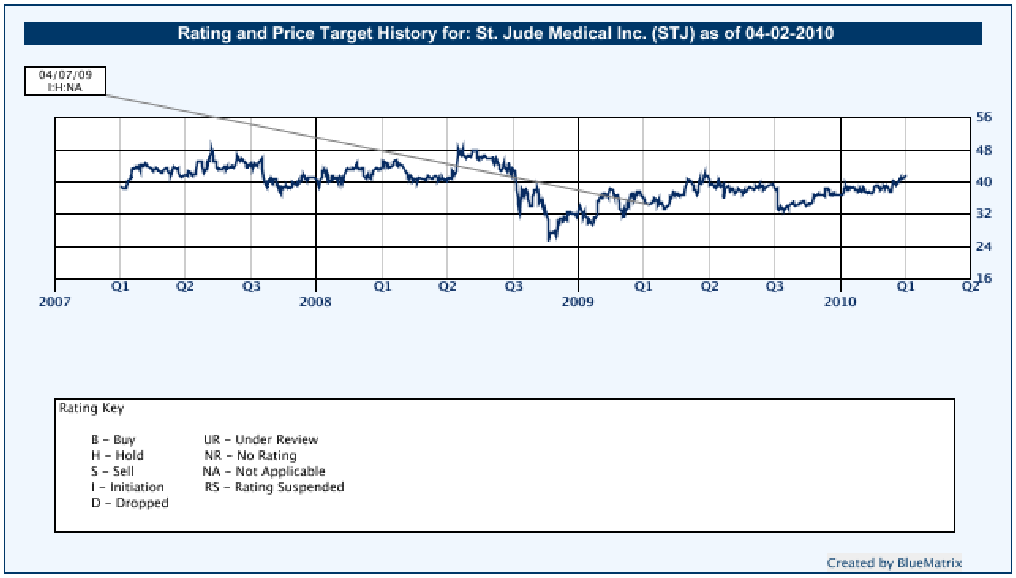

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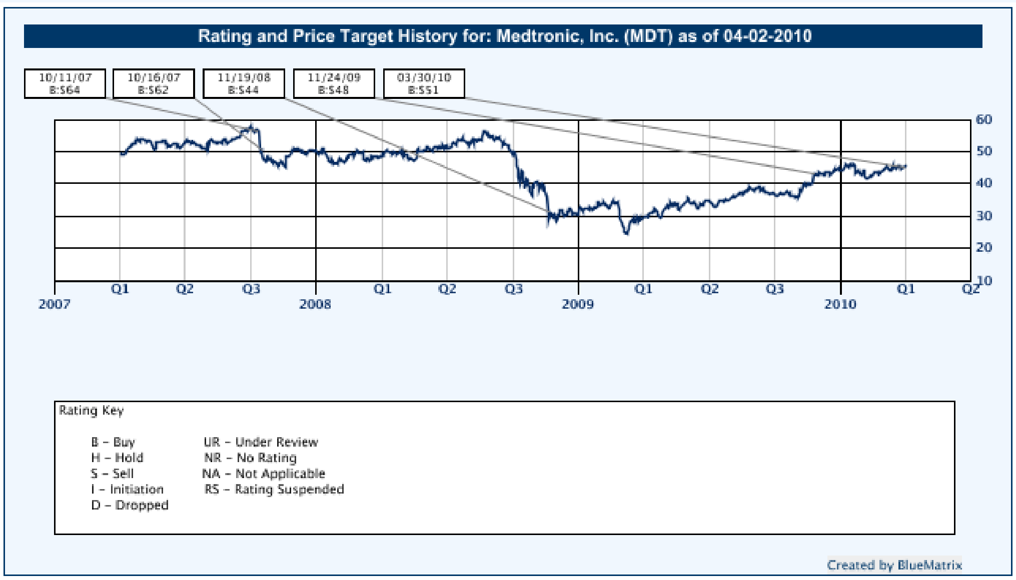

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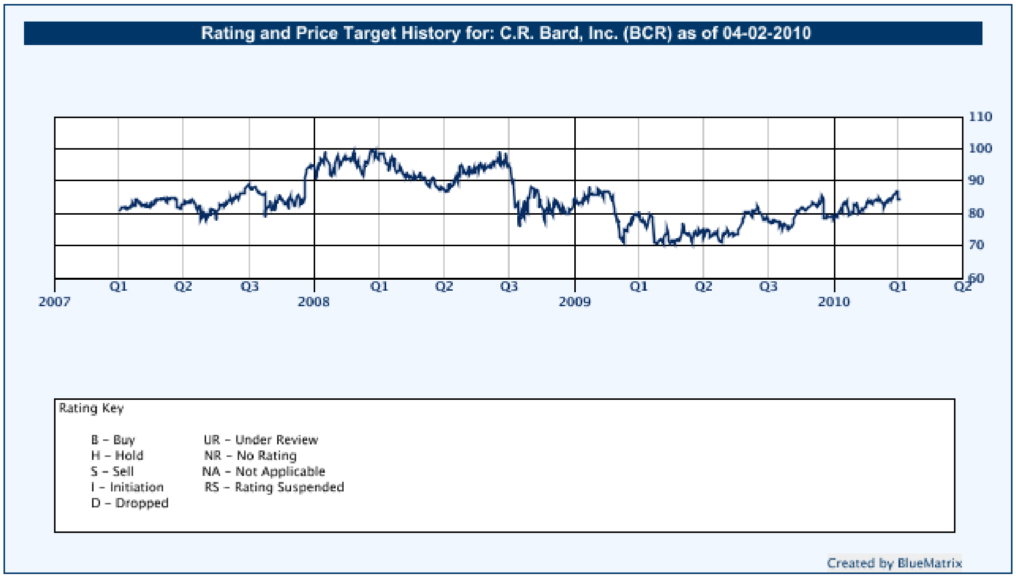

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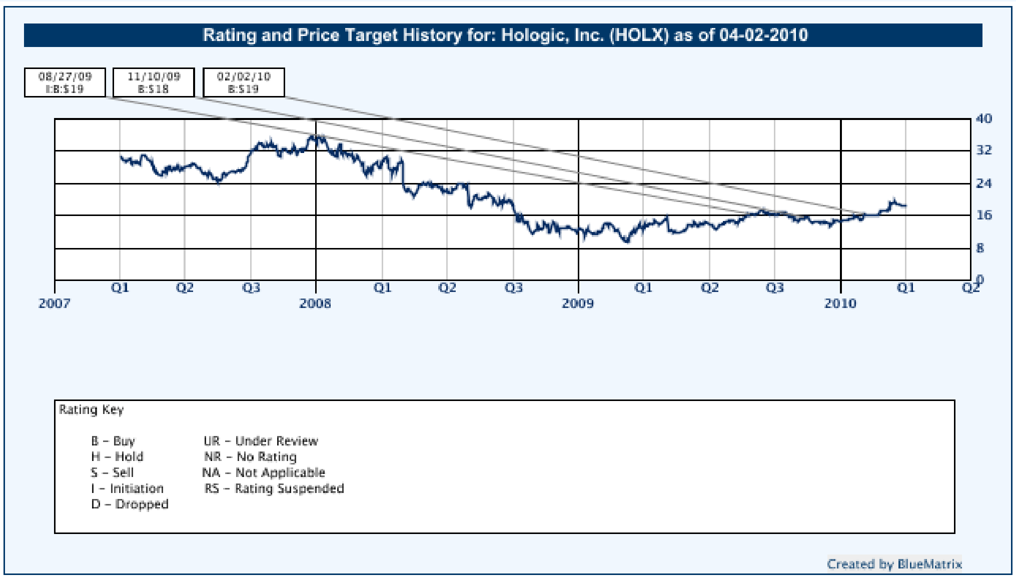

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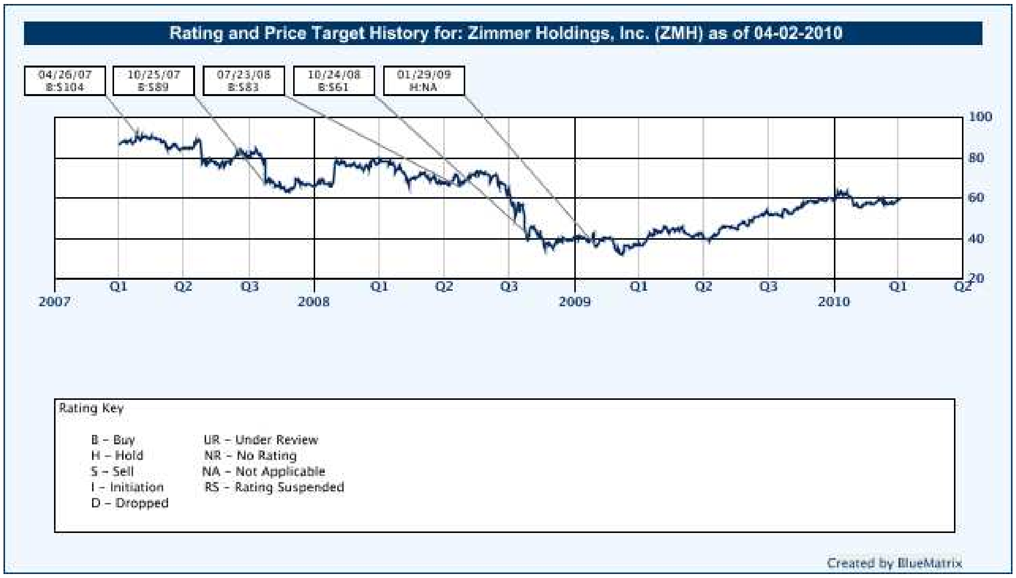
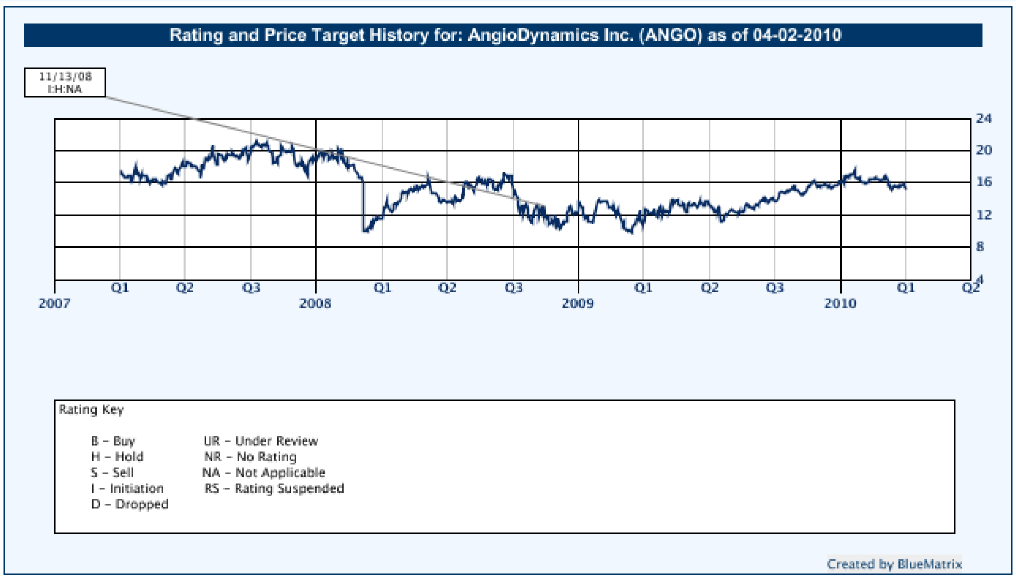


AngioDynamics Inc.



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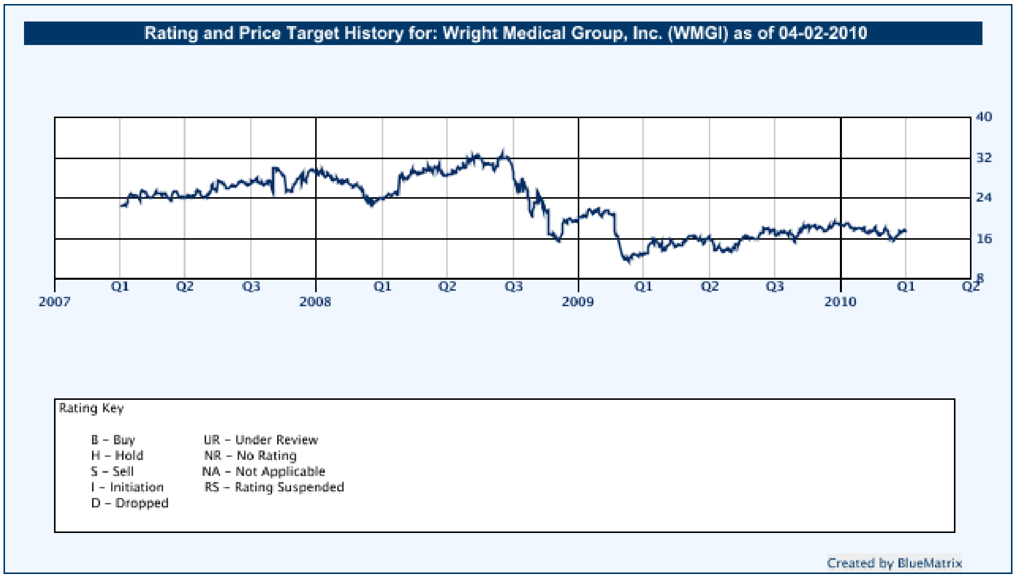

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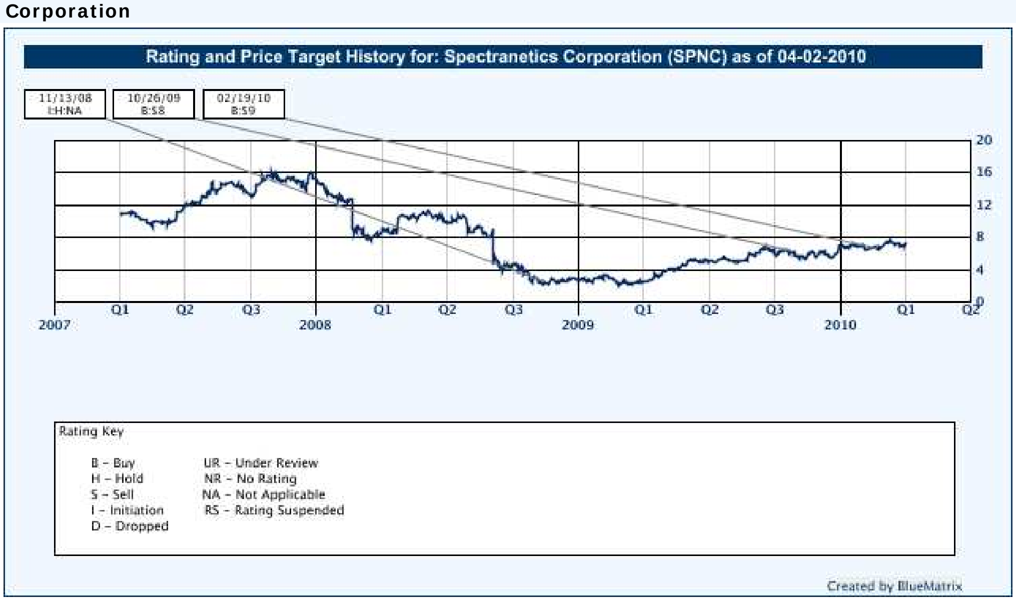

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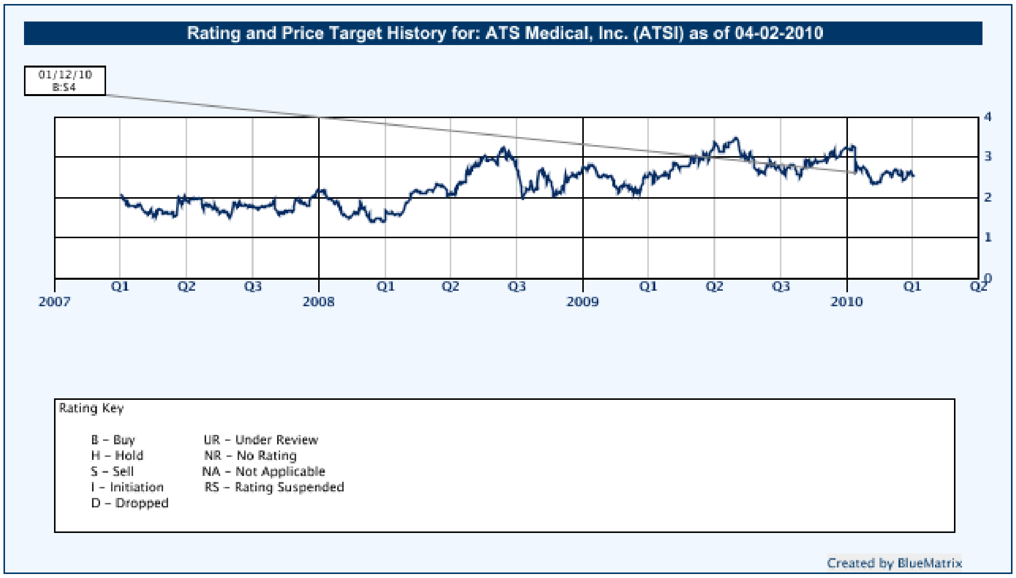

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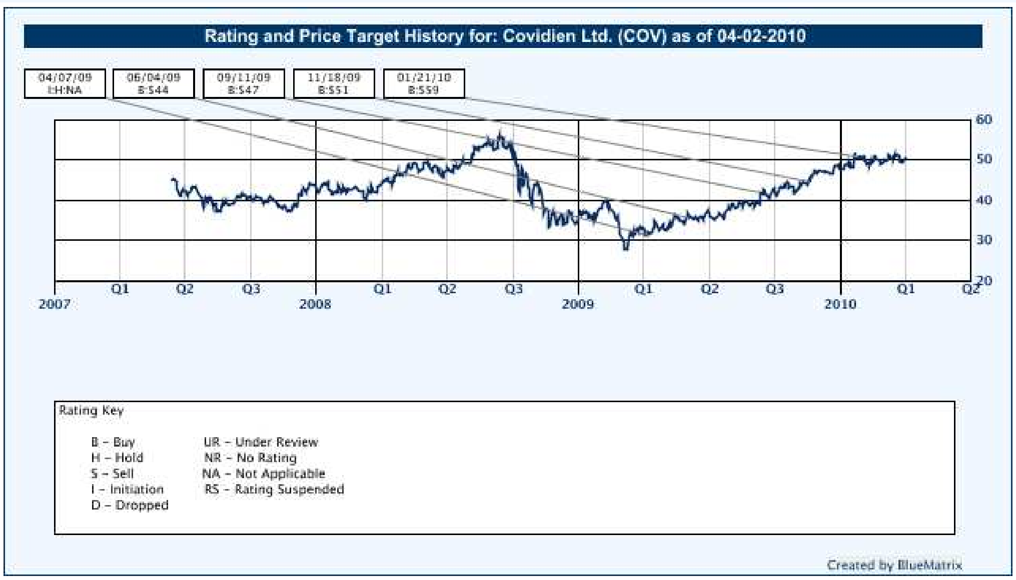

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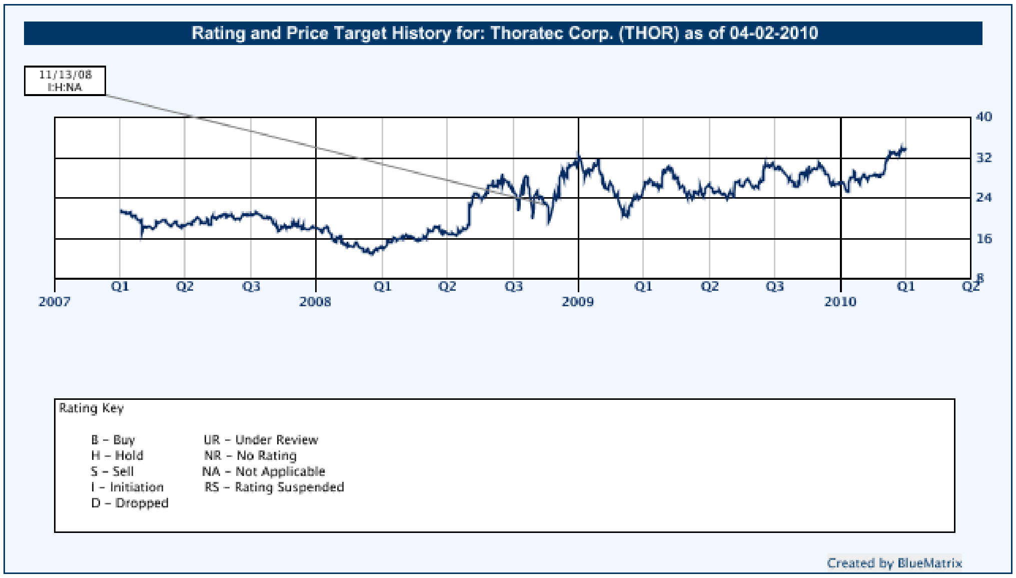

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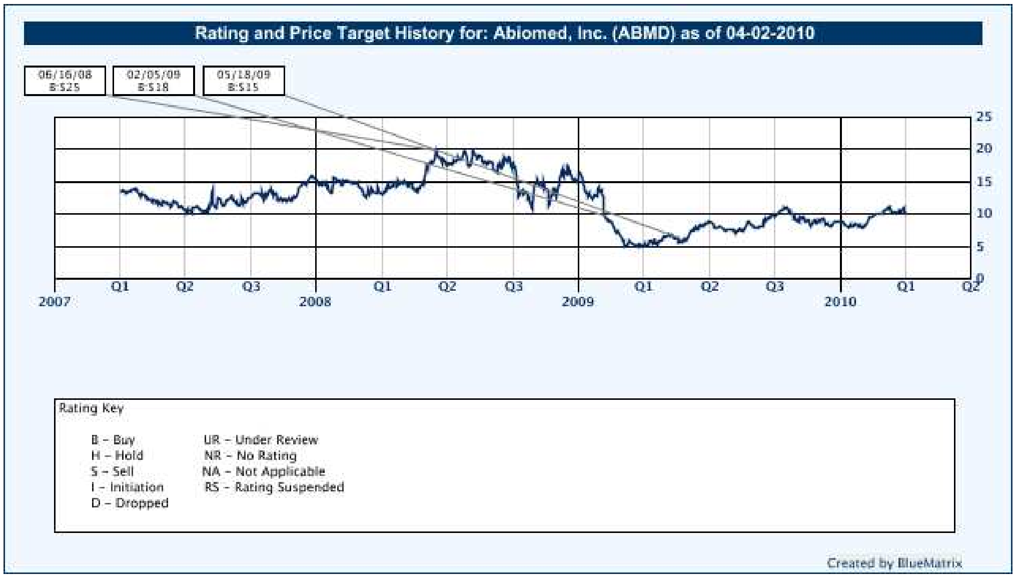

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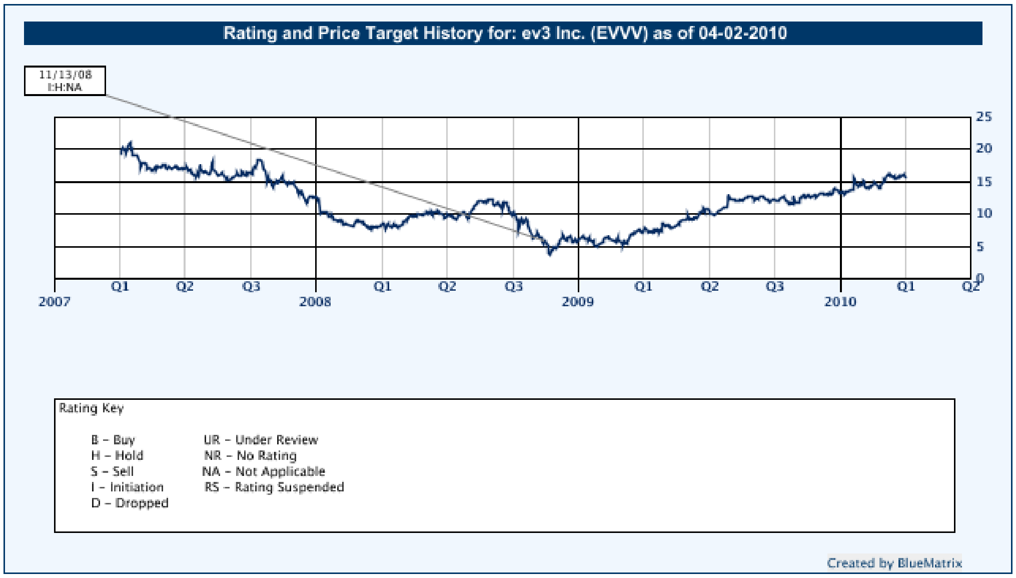
ev3 Inc.



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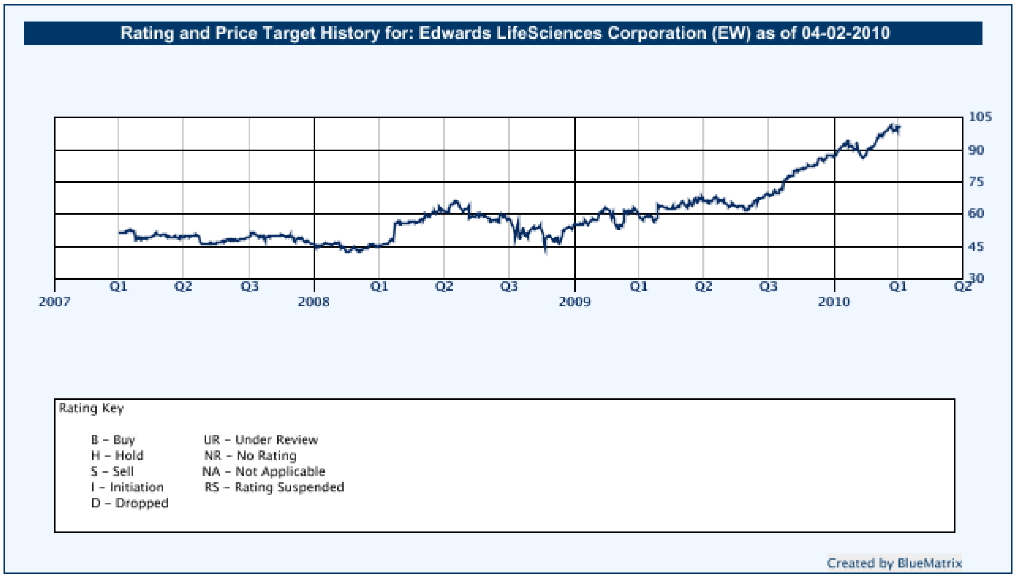
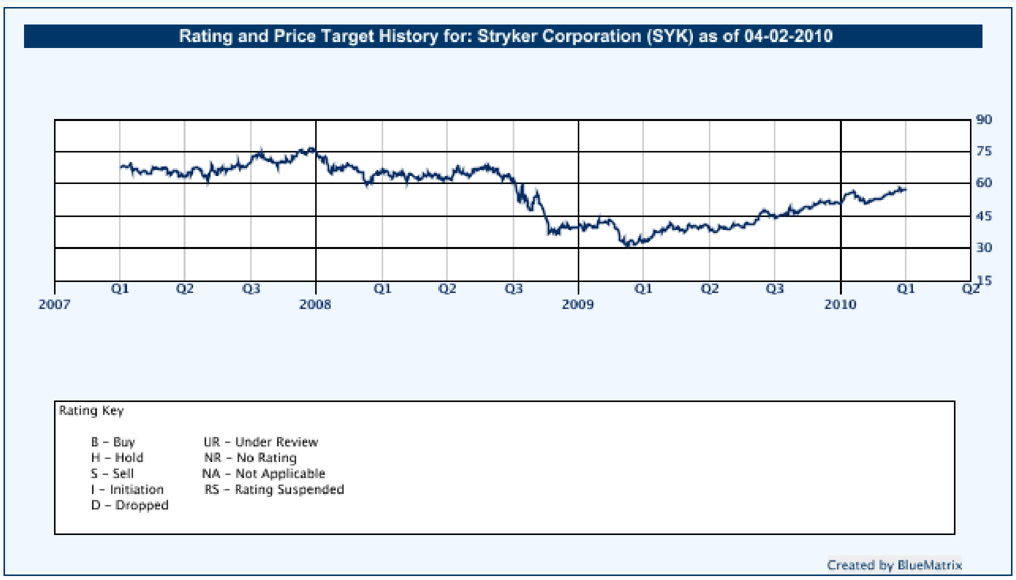


Stryker Corporation



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A Breakdown of Medical Device Trends

GLENN J. NOVARRO RBC CAPITAL MARKETS CORP.

GLENN J. NOVARRO has been a Senior Analyst covering the medical supply and device sector for over 10 years. He is a Managing Director for RBC Capital Markets Corp. Mr. Novarro joined RBC in October 2008, and he covers 17 large- and small-cap companies. Prior to joining RBC, Mr. Novarro covered the sector for Banc of America Securities and Credit Suisse.

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SECTOR — MEDICAL DEVICES

(ABF809) TWST: Now that health care reform is in place, how do you feel it will affect the medical device space and particularly the sectors you cover?

Mr. Novarro: I would like to answer this in two ways for you, first from a stock point of view and second from a pure fundamental point of view, as it relates to sales and earnings. From a stock point of view, the fact that we've had some resolution has been a positive, as it removes an overhang from the sector. And portfolio managers will be more willing to invest in the sector knowing that the noise out of Washington should be less going forward. From a sales and earnings point of view, there is minimal near-term impact because most of the taxes and fees won't kick in until 2013, and the volume benefit from health care reform won't kick in until 2014 and beyond. Longer term, I believe that health care reform will be more of a positive than a negative for my sector. The big positive from reform should be an increase in procedure volume. More patients should be treated with medical devices, particularly patients who are non-Medicare. We believe that the largest beneficiaries of health care reform will be orthopedic and spine companies. The offset that some investors worry about is government intervention. Do we see pricing pressure on medical devices? Pricing pressure would come predominately from hospitals that purchase the devices outright. But for a hospital, the benefit of reform is that bad debt expense should go away. Bad debt expenses occur when an individual without insurance enters the emergency room or has to be treated for days because of trauma or some major ailment, and of course the hospital cannot collect from that individual. So with reform, as hospitals treat more patients with insurance, bad debt expense should drop dramatically and the profitability of hospitals should improve. As profitability improves, hospitals will not feel the pressure to push back on medical device pricing. As a result, medical devices should not face pricing pressure. Net-net, I believe that health care reform is going to be a positive for medical device companies. Volumes should go up and more than offset any unusual pricing pressures.

Highlights

Glenn J. Novarro discusses the major events and trends that will influence the medical device sector moving forward, including health care reform and the macro economy. The analyst mentions several specific devices that should see market growth. Mr. Novarro expects to see momentum in orthopedics, as increased demand comes from those younger patients who put off such procedures in the economic downturn. He warns of uncertainty in the sector in the near term but recommends an "overweight" position to longer-term investors.

Companies include: Boston Scientific (BSX); St. Jude Medical (STJ); Medtronic (MDT); Edwards Lifesciences (EW); Stryker (SYK); Abbott Laboratories (ABT); Wright Medical Group (WMGI); Johnson & Johnson (JNJ) and Zimmer Holdings (ZMH).

TWST: What about the economy? Whether you think the recession is over or receding, how has it affected this space? I've heard divided opinions on the affect of patients' inability to purchase necessary medical items/procedures due to the recession.

Mr. Novarro: The recession has impacted only a handful of my companies. Within my cardiovascular subsector, which includes companies like **Boston Scientific** (BSX), **St. Jude Medical** (STJ), **Medtronic** (MDT) and **Edwards Lifesciences** (EW), there has been very little impact. These companies are selling stents, pacemakers, ICDs and heart valves. Most of the patients that receive these devices are elderly and are over the age of 65, and therefore qualify for Medicare. And since the government is paying for these procedures, we saw very little impact on cardiovascular implant volumes, especially in 2009, during the height of the recession. Conversely, the slowing global economy impacted orthopedic and spine volumes, as the recipients of these devices are much younger. For instance, over 80% of cardiovascular implants today go to Medicare patients. That compares to 60% for orthopedic and spine implants. So orthopedic and spine cases tend to involve younger individuals. In 2009 many younger patients decided to delay receiving a new knee or hip because they feared losing their job while out on rehab. As such, orthopedic and spine companies experienced a slowdown in procedure volumes last year due to the economy but are seeing a gradual recovery in volumes year to date. Several other medical device segments were impacted by the economy, such as contact lenses, diabetes monitors and strips, and aesthetics. The cost of these devices are out of pocket. They are not covered by commercial insurance or Medicare, and thus there has been a slowdown in consumption.

"We believe that Abbott Labs is a 13% to 14% earnings grower. Trading at 11 times earnings, we view the shares as undervalued. We think that the market probably assumes Abbott is closer to a 10% earnings grower."

1-Year Daily Chart of Abbott Laboratories

Chart provided by www.BigCharts.com

TWST: What are some of your top stock picks at the moment and why?

Mr. Novarro: Our top stock picks by subsector are as follows: In the medical supply space, we favor **Abbott Labs** (ABT). We believe that **Abbott Labs** is a 13% to 14% earnings grower. Trading at 11 times earnings, we view the shares as undervalued. We think that the market probably assumes **Abbott** is closer to a 10% earnings grower. If our earnings forecast proves correct, there is significant p/e multiple expansion on the horizon for **Abbott**. In the cardiovascular space, our favorite name is **St. Jude Medical**. In our opinion, **St. Jude Medical** should be the primary beneficiary of the recent **Boston Scientific** ICD recall. And then lastly, in the orthopedic space, our favorite name is **Stryker** (SYK). **Stryker** should benefit from, one, a recovery in the economy and an acceleration in knee and hip implant volume trends, and two, hospital spending returning in 2010. Almost half of **Stryker**'s business is medical equipment sales to hospitals that's in the form of surgical equipment, endoscopy equipment, and beds and stretchers.

TWST: Are there any companies that you have a "sell" on or that you are not as confident about?

Mr. Novarro: The one stock that we have an "underperform" rating on is **Wright Medical** (WMGI). The stock has not performed well over the past two years. **Wright Medical** is a company that competes in the knee and hip space but is at a competitive disadvantage relative to the bigger players, such as **J&J** (JNJ), **Stryker** and **Zimmer** (ZMH). **Wright** is also a company that needs to continue to spend more to remain competitive. This is not a formula for strong earnings growth. And at these valuations, this is an orthopedic name that we've been telling investors to avoid.

TWST: Are there any companies whose products address unmet market needs and could seriously impact company growth? A company that might be revolutionary or a big earnings driver?

Mr. Novarro: Yes, and that company would be **Edwards Lifesciences**. The growth of the medical device sector has always been based on taking open surgeries and making them minimally invasive. So when you think about what was the benefit years ago of introducing balloon angioplasty or developing coronary stents, it was to do less open-heart surgery. In other words, fix the heart through minimally invasive techniques. That approach is now being applied to traditional heart valve surgery. Today if someone has a valve that needs to be replaced, we either open the chest or we make smaller incisions in between the ribs. Nonetheless, it's a three- to five-hour procedure and individuals will be in the hospital for five to seven days. And even though the success rate for these operations is very high for those who are over the age of 65, open-heart surgery is not the best option for many patients. **Edwards Lifesciences** has been a pioneer in developing better heart valves for open surgery. And now they are pioneering a minimally invasive approach to replacing damaged heart valves. **Edwards** has developed a new valve called Sapien. It can be delivered through a small incision in the groin known as the "transfemoral approach," the same approach that a surgeon would use, for instance, to implant a stent. The company has also developed a second approach called the "transapical approach," where the surgeon enters the heart through a small incision in between the ribs. By far this is expected to be the most exciting medical technology advancement over the next couple of years.

Medtronic is also a player in minimally invasive valve replacement. They entered the space toward the end of 2008 through the acquisition of a company called **Corevalve**. Both **Edwards** and **Medtronic** are in the European market, and the European market has gone from zero to over $200 million in just a few years. **Edwards** should be launching into the U.S. market by the end of 2011 or early 2012, and the company has a two-year lead on **Medtronic**. In the U.S., I believe that the minimally invasive approach to valve replacement will be a $1 billion market opportunity. In our view, **Edwards** has the best technology and Sapien will not only have a very favorable impact on the company's top line, but this is an 85% to 90% gross margin product. So it should also significantly lift the company's operating margins and earnings growth rate.

TWST: As you talk to management across the sectors you cover, what's their level of confidence for growth?

Mr. Novarro: Executives in this space are very positive about the market opportunities that lie ahead. For instance, a cardiovascular executive looks at the ICD market and sees strong growth ahead, given the aging of the Baby Boomers and how underpenetrated the market is. An executive in the ortho and spine space would say the same thing. So most executives feel that patient demographics are quite positive and market penetration rates remain low, and that there is a significant opportunity to continue to grow both top line and bottom line. The one negative that I constantly hear from the executives in the medical device space involves the FDA. The FDA today is rejecting more drugs and devices than ever before. The FDA is not appropriately staffed, according to many medical device executives, and it's for this reason that review times are taking longer. I think the FDA is the biggest concern among medical device executives today.

"I find that portfolio managers are most interested in the orthopedic space — that would be companies like Stryker and Zimmer. And the interest here lies with the fact that orthopedic companies should benefit from an improving economy and falling unemployment."

1-Year Daily Chart of St. Jude Medical

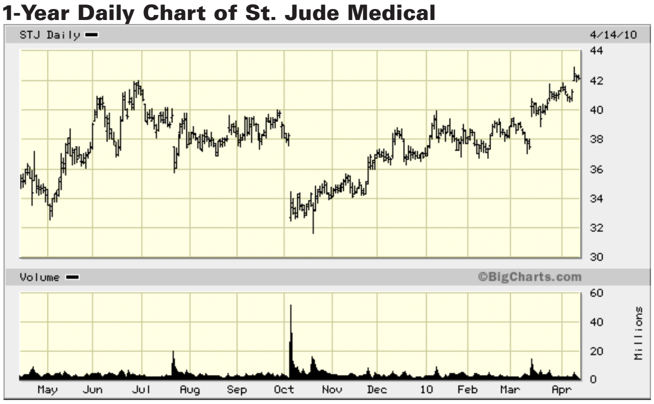

Chart provided by www.BigCharts.com

TWST: On the flip side, what's investor interest like in the space at the moment?

Mr. Novarro: It's very mixed right now. But I would say for the most part, there is less interest in the space today than at the beginning of the year. As the economy starts to improve in the U.S. and as unemployment drops, there are sectors that are clearly more levered to these trends, such as retail, industrials and technology. And you are already seeing companies in these sectors put up strong quarterly results and issue above-consensus guidance. So most portfolio managers today are building positions that will take advantage of an improving economy. And like I said earlier, cardiovascular device companies are not tied to the economy. Moreover, portfolio managers often invest in diversified companies like **Abbott Labs** and **Johnson & Johnson** as a way to play defense during periods of economic uncertainty. We are in a period where investors believe the economy is getting stronger. Thus, there is less interest in defensive names, such as **Johnson & Johnson** or **Abbott**. I find that portfolio managers are most interested in the orthopedic space — that would be companies like **Stryker** and **Zimmer**. And the interest here lies with the fact that orthopedic companies should benefit from an improving economy and falling unemployment. Individuals deferred knee and hip implants last year because they were worried about job loss. As these individuals feel more comfortable about their employment status, they are very likely to return in 2010 for a procedure. And so you'll see an acceleration in knee and hip implant volumes in 2010.

TWST: What are you advising investors to do now?

Mr. Novarro: For investors that can take a 12-month view and can be longer-term investors, we continue to recommend an "overweight" position in the sector, as the earnings power remains quite strong. Again, our favorite names are in the diversified medical supply sector, **Abbott**; in the cardiovascular sector, **St. Jude**; and in the orthopedic sector, **Stryker**.

TWST: As people on the Street discuss the space, do you feel there's anything that's being overlooked or misunderstood by fellow analysts?

Mr. Novarro: No, I'd say that the market is quite efficient. But when it comes to analyzing the sector, there are a lot of unknowns at the moment. For instance, in my cardiovascular sector a month ago, in a very unprecedented move, **Boston Scientific** pulled all their ICDs from the U.S. market, and so that's having a direct impact on the sector here in the near term. **Medtronic** and **St. Jude** should benefit near term, but **Boston Scientific** at some point will come back to the market. **Boston Scientific** hopes to be back into the U.S. market in the middle of April, but that's in the hands of the FDA. And the FDA is a very unpredictable body these days. Currently, the shares of **Boston Scientific** are under pressure because the company is off the U.S. ICD market, and this should have a negative impact on 2010 sales and earnings. Meanwhile, this is a nice positive for **Medtronic** and **St. Jude**, as both companies should pick up ICD market share, likely driving better-than-expected sales and earnings growth in 2010. As such, both stocks have performed better of late, especially since the **Boston Scientific** recall, which occurred in mid-March. But over the next month or so, there should be a little more clarity as to when **Boston Scientific** comes back to the market. And once they do return to the U.S. market, there should be less volatility in the cardiovascular space. I also believe that the **Boston Scientific** ICD recall is impacting the orthopedic space. There are some investors that have pulled money out of the cardio sector because of the uncertainty that's been created by the **Boston Scientific** recall, and put their money into a typically more predictable sector, such as orthopedic and spine. So in the near term, there is uncertainty in the medical device sector. But over the next four weeks or so, this is expected to be resolved, and it should become a bit easier to invest in the sector.

TWST: Thank you. (MRR)

Note: Opinions and recommendations are as of 04/05/10.

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ANALYST INTERVIEW

A Search for Share Gainers in Med Tech

DERRICK SUNG — SANFORD C. BERNSTEIN & CO., LLC

DERRICK SUNG, PH.D., joined Sanford C. Bernstein & Co., LLC, in 2008 as the Senior Research Analyst covering U.S. medical devices. Prior to joining Bernstein, he was Director of Marketing and Business Development for the neuromodulation division of Boston Scientific Corporation. Dr. Sung also spent four years as a Management Consultant with the Boston Consulting Group, where he advised med tech and biopharma companies on a variety of strategic and operational issues. Dr. Sung began his career as an R&D Engineer for Guidant Corporation, now part of Abbott Vascular. He holds a Ph.D. in bioengineering from the University of California, San Diego, an MBA from San Diego State University and a B.S. in mechanical engineering from Stanford University.

SECTOR — MEDICAL DEVICES

(ABF808) TWST: How, if at all, will the recently passed health care reform affect the sector as you cover it?

Dr. Sung: I think you need to look at it from both a near-term as well as a longer-term perspective. The near-term impact of health care reform on the medical devices sector stems from the medical device industry tax. This is a 2.3% excise tax on device sales which would begin in 2013. The impact of that tax on the large-cap device companies, I think, ends up being quite manageable. By our calculations, it will affect earnings for our companies negatively by about 3% or 4%, basically in the low-single-digit range. Some of that gets offset, however, by the benefit of expanding coverage to an additional 32 million Americans. Our analysis shows that expanding coverage could grow the revenue base of the large med tech markets, like orthopedic or cardiovascular implants, by 3% to 7%. So if you put it all together, I think you may see a net negative impact of maybe a couple percent to the bottom line for these companies, which is not that big of a deal.

The other question is how might health care reform impact medical device pricing. Again, over the near term, I think it will be relatively benign. The hospitals directly purchase medical devices from the manufacturers, so if hospitals benefit economically from extending coverage to the uninsured, this could potentially ease some of the pricing pressure device companies are currently seeing.

Highlights

Dr. Derrick Sung takes readers through his mid- and long-term predictions for the medical devices space, specifically highlighting the short- and long-term effects that health care reform and the economic recovery will have on the industry. Overall, Dr. Sung expects to see additional multiple expansion across the sector and believes there are still opportunities to be found among the med tech names. Companies include: Zimmer Holdings (ZMH); St. Jude Medical (STJ); Boston Scientific (BSX); Medtronic (MDT); Stryker (SYK); Abbott Laboratories (ABT) and Johnson & Johnson (JNJ).

Now over the long term, there are some provisions within the health care reform package that could have a much more negative impact on medical device pricing. There are provisions in the bill that establish demonstration projects around bundling of hospital payments and gainsharing, which could dramatically alter the payment and purchasing dynamics between device companies and hospitals. Hospitals purchase medical devices, but it's the physicians who usually make the decision around which devices to use and when. Under Medicare today, physicians and hospitals are reimbursed under two separate payment systems, so there's no direct incentive for doctors to think about the cost of devices when making their treatment decisions. As a result, device manufacturers have been able to maintain pricing power by marketing their products directly to physicians. Under the bundling programs, the big change is that a single lump-sum payment would be made for a specific procedure, say, a hip implant, and that payment would cover the costs for both the hospital and the physician. The physician would also be allowed to share in any of the cost savings that are generated. This would be the gainsharing aspect of the program. As a result, the physician and the hospital would now suddenly be aligned and incentivized to manage costs down, which could have a very negative effect on the ability of the device com-

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panies to maintain pricing. What I'd stress, however, is that programs like these are at least five or more years away from implementation because the health reform bill establishes demonstration programs which would not be complete until 2016. And only after data comes in from these pilot programs will CMS even begin to think about rolling such changes out on a wide scale.

TWST: What about the other issue that has been on everybody's minds for as long as the proposed health care plan, if not longer? How is the economy affecting the sector currently?

Dr. Sung: I think the economy has affected this sector in two ways. The first is from a hospital purchasing and pricing perspective. This is because the hospitals have been under significant economic strain as a result of the economic downturn. In turn, they have become more aggressive in trying to drive pricing discounts from the medical device manufacturers. So we're seeing increased pricing pressure from the hospitals as a result. Also the hospitals have had to cut back substantially on their capital spending. So device companies who sell products that are paid for from hospital capital spending budgets, such as hospital beds, have seen marked declines in their sales.

"Zimmer should benefit from the recovery of the orthopedic markets in the back half of the year, as pent-up demand drives above-average growth. In addition, Zimmer will benefit from a favorable product cycle."

1-Year Daily Chart of Zimmer Holdings

Chart provided by www.BigCharts.com

The economy has also had an impact on procedure volumes in markets where the devices are used in more elective-type procedures. For example, in orthopedics, we saw patients deferring hip and knee replacement surgeries when the economy turned down. Unemployment played a role, but the bigger driver of these deferrals appeared to be tied to consumer sentiment. Many patients did not want to take time off from their jobs for fear of losing them, and there was also an increased level of sensitivity to the out-of-pocket copays.

Out in Europe, we're also seeing the economy impact procedure volumes and pricing, but for a somewhat different reason. Most European countries operate under a single-payer national health care system. As the various governments saw their economies come under pressure, they cut back on their national health care budgets. This trickled down to regional hospitals who then had to cut back on the number of elective hip and knee procedures that were being done.

TWST: Do you see that situation changing now and possibly into the next couple of quarters?

Dr. Sung: In the U.S., I would expect to see the orthopedic reconstruction markets begin to recover in the back half of this year. These are hip and knee surgeries that are getting deferred but eventually will need to get done as the patients are not going to be able to live with their pain forever. Our checks suggest that the procedure deferrals have stabilized, and I think we're going to see some pent-up demand drive growth for hip and knee implants in the back half of 2010 in the U.S.

Out in Europe, I think that's a much slower recovery, so I would not expect Europe to recover in this year. I expect the hip and knee markets there to remain depressed but stable. I think that's going to be a slower road to recovery because it's more tied to national economies out there.

TWST: What about your top stock picks at the moment? What are they and why?

Dr. Sung: In the ortho space, I like **Zimmer** (ZMH). **Zimmer** makes the hip and knee implants that we were just talking about. **Zimmer** should benefit from the recovery of the orthopedic markets in the back half of the year, as pent-up demand drives above average growth. In addition, **Zimmer** will benefit from a favorable product cycle. They recently launched two new hip products and a knee product at the end of 2009. These products will drive positive mix for the company starting the middle of this year. Their new hip products should also drive some modest share their way as well. So between the market recovery and their product cycle, I think **Zimmer** is very nicely positioned.

In the cardio space, I like **St. Jude Medical** (STJ). **St. Jude** makes implantable defibrillators known as ICDs. I like **St. Jude** because they have a nice share gain story associated with them. First, **St. Jude** is going to benefit from a recent product recall by their competitor, **Boston Scientific** (BSX), who pulled all of their ICD devices off the market as a result of a manufacturing process change which was not appropriately filed with the FDA. In addition to that, **St. Jude** is also entering into a favorable product cycle as they are launching their a new ICD platform in mid-2010. This should also drive share their way. Finally, **St. Jude**'s ICD share will benefit from what we term the "ICD replacement cycle." The replacement cycle refers to the fact that these implantable defibrillators are battery-powered devices and every five years to seven years, the devices need to be replaced when their batteries run out. In the vast majority of cases, a physician will replace an ICD with a new one from the same manufacturer. Back in 2005, **St. Jude** gained nearly nine points of market share when **Boston Scientific** had their first ICD recall. Beginning in the back half of 2010 and through 2011, these patients will come up for replacement and the sales of these replacement devices will benefit **St. Jude**.

TWST: Is there any company at the moment with a

potentially game-changing product that is particularly innovative or meets an unfulfilled market need?

Dr. Sung: I cover the large-cap medical device names. My coverage universe includes **St. Jude**, **Medtronic** (MDT), **Boston Scientific**, **Zimmer**, **Stryker** (SYK), **Abbott Labs** (ABT) and **Johnson & Johnson** (JNJ). Among these companies, I think **St. Jude** is best positioned from an emerging-technology perspective because they have strong plays in the atrial fibrillation (AF) and neuromodulation space. Atrial fibrillation involves the use of a catheter to treat an irregular heart rhythm disorder that can give rise to potentially fatal strokes. Today medical management is the primary method of treatment for these patients, but a good number of these patients either do not respond well or cannot tolerate the side effects. So catheter-based ablation to treat AF fulfills an unmet need and could grow into a multibillion-dollar market.

Neuromodulation involves delivering electrical signals to different parts of the body to achieve a given therapeutic effect. Currently, **St. Jude** sells a spinal cord stimulator, which delivers electrical signals to the spinal cord to treat patients suffering from chronic pain. This is a $300 million-plus business that is growing in the mid-teens. The growth opportunity for **St. Jude**'s neuromodulation business lies not only in this rapidly growing segment but also in the potential to use this technology to treat new indications, such as depression, Parkinson's disease, obesity and migraine headache. These could all develop into huge markets if the technology pans out.

The current contribution of both of the AF and neuromodulation businesses to **St. Jude**'s growth today is rather small, however. So I'd emphasize that these are technologies which I believe will take three or four more years to develop into meaningful growth drivers for the company.

TWST: What about investor confidence in the sectors that you cover at the moment? I know this requires some generalization, but what is the level of confidence?

Dr. Sung: I think on the one hand, there is an appreciation that the medical device companies supply a critical need for an aging population, so the med tech markets are never going to go away. On the other hand, investors are recognizing that underlying growth is slowing in the key markets that make up the sector, such as orthopedic implants, drug-eluting stents and cardiac rhythm management devices. In the late 1990s through the early part of this decade, we were seeing high-double-digit growth in all of these core markets. Over the past few years, we've seen market growth slow to the mid-single-digit level, which is where we're at today. The drug-eluting stent market, for example, is even potentially in decline. That has forced investors to change the way they view the sector now, as one can no longer think of med tech as a pure growth sector.

Then I think there's also a bit of an overhang from health care reform that's still sitting over my sector — all of health care in general for that matter. Whereas before there was uncertainty as to the passage and the content of the health care reform bill, now there remains some uncertainty as to what the impact of the bill that got signed will actually have on the med tech companies. As I mentioned earlier, I believe that in the near to medium term, the impact of health care reform will be really quite manageable for the sector, but I think it will take a bit of time for investors to become totally comfortable with this. As we gain more clarity on the impact that the health care changes will have, I think investors will coming back into the sector a bit more.

> ***"Whereas previously the focus might have been on which company has the technology to allow it to participate in the fastest-growing markets, I think now investors need to focus on which companies will be share gainers within their respective markets and which companies might have greater opportunities for margin expansion."***

TWST: What are you advising them to do?

Dr. Sung: I think investors can still find opportunity within the sector. However, with growth slowing in the major end markets and with the potential for emerging technologies to drive meaningful growth still a few years away, I think investors need to slightly shift the way they approach these stocks. Whereas previously the focus might have been on which company has the technology to allow it to participate in the fastest-growing markets, I think now investors need to focus on which companies will be share gainers within their respective markets and which companies might have greater opportunities for margin expansion. New product cycles become more important to look at, as companies that are entering into new product cycles often have the best chance of gaining market share. Investors also need to look at how well the companies are run from an operating perspective, as the companies can no longer depend on the top line alone to drive earnings growth.

Additionally, I do think that we will see some further multiple expansion across the sector. The lifting of the health care reform overhang should help that. Also the sector is trading at around a 13 times forward earnings multiple as compared to the S&P, which is trading around 15 times. In general, the med tech companies are still seeing high-single-digit to low-double-digit earnings growth, so I would expect to still see multiples expand across the sector.

TWST: Thank you. (MRR)

Note: Opinions and recommendations are as of 04/05/2010.

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12-Month Rating History as of 4/10/2010

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BSX - M (RC) 1/21/2010, O (IC) 5/22/2009, O (DC) 6/13/2007

MDT - M (IC) 5/22/2009, O (DC) 6/13/2007

STJ - O (IC) 5/22/2009, O (DC) 6/13/2007

SYK - M (IC) 5/22/2009, M (DC) 6/13/2007

ZMH - O (RC) 9/21/2009, M (IC) 5/22/2009, M (DC) 6/13/2007

JNJ - M (IC) 5/22/2009, M (DC) 6/13/2007

ABT - O (IC) 5/22/2009

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A N A L Y S T   I N T E R V I E W

Annual Checkup on the Medical Device Space

DR. SEAN LAVIN, M.D. — LAZARD CAPITAL MARKETS LLC

DR. SEAN LAVIN, M.D., is a Senior Analyst covering the medical technology space. He joined Lazard Capital Markets LLC in March 2008. Previously, Dr. Lavin was a sell-side Analyst at Oppenheimer and Co., covering medical devices and diagnostics. He focuses on minimally invasive devices and those that he believes can change the standard of care. Prior to joining Oppenheimer, he worked as a Surgical Resident at Mount Sinai Medical Center in Miami Beach, Fla. While there, Dr. Lavin participated in general, plastic, trauma, vascular, cardiothoracic and urologic surgery cases, and he cared for patients in the ICU, emergency room and burn unit. Dr. Lavin has an M.D. from Ohio State University College of Medicine and a B.S. in chemistry with a minor in biology from the Massachusetts Institute of Technology.

SECTOR — MEDICAL DEVICES

(ABF803) TWST: How have the prospects for the medical devices industry changed, if at all, since the last time we spoke?

Dr. Lavin: I don't think it has changed much. I mean, we spoke recently enough that the ideas in the health care plan were certainly very similar to what was passed, and if anything the markets have opened up a little bit more and you see more financings for smaller companies. So maybe the atmosphere has gotten a little bit better for startup companies, but I don't think there has been any major changes the last four or five months.

TWST: What are the major trends and how have they changed since the passage of health care reform? What is your take on the status of the economy right now?

Dr. Lavin: I think the last time, we talked about capital spending and health care reform, and probably the FDA getting a little stricter. I think that many of those things still exist — the capital spending. Certainly hospitals are spending a little bit more now than a year ago, but I don't think we're back to kind of 2007 or early 2008 levels. So there is still some restriction on spending in some hospitals. The FDA, I think, most people still expect to look for more data and fewer 510(k)s, and to be a little bit stricter on invasive devices. But the agency is still looking for more money and still hasn't gotten exactly what direction it is going to go under the new administration. And I think the reform plan pretty much went through with most of the expectations that have been around for the last few months. And I think it's going to make a reasonable difference whether or not the Senate votes on reform stick or if the house changes get passed because that moves the device tax out from, I think, 2011 to 2013. That's really the only, I think, big worry from the reform for device companies.

TWST: And the economy?

Dr. Lavin: It's probably gotten a little bit better. In the last six months, if we look at some of the stocks, there are some of the companies that are more economically driven. Companies like **Allergan** (AGN), they have certainly picked up their sales in the last two or three quarters. So it's certainly improving.

TWST: What are your top stock picks at the moment and why?

Dr. Lavin: We continue to like **Covidien** (COV). I'll go through why in a second. We like **Endologix** (ELGX). We just upgraded **Medtronic** (MDT) to a "buy," and I like **Varian** (VAR) and **HeartWare**

Highlights

Dr. Sean Lavin doesn't see much change in the medical devices market since one year ago, although he does believe access to capital has become more available to smaller and startup companies. Although he does admit hospital spending has increased over the past year, he says it still has not reached 2007-2008 levels. The analyst offers his top industry picks and discusses several additional trends, including supply-demand imbalance and health care reform, that will affect this space.

Companies include: Allergan (AGN); Covidien (COV); Endologix (ELGX); Medtronic (MDT); Varian Medical Systems (VAR); HeartWare International (HTWR); Boston Scientific (BSX) and Thoratec (THOR).

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(HTWR). And then on reasons why, just going through them one by one — **Covidien**, we think they're growing their highest-margin devices fastest, including most complex surgical tools, which is expanding margins and profits. They are very economically safe. Almost every device **Covidien** sells is relatively cheap and doesn't have its own reimbursement, so there is very little risk around that. They are almost entirely pointed towards necessary surgical and medical procedures, so there is very low economic risk around need.

"I think hospitals cut back some of their inventories probably two to four quarters ago, so we haven't seen a big imbalance recently. It seems that after they made those cuts, that companies have seen more normalized growth. So I don't think there is at least imbalance right now unless you want to look at ICDs."

When you look at **Varian**, we think they have the most efficient and probably the most cost-effective radiation therapy devices, which is required medical treatment, not something people can put off for cancer. And as the economy has gotten a little bit better, hospitals seem to be picking up capital spending a little bit and their orders seem to be improving.

Endologix is a company that makes a stent for abdominal aortic aneurysms, and we think their method of building that stent from the bottom of the aorta up from bifurcation is a better method than the competitors, **Medtronic**, **Cook** and **Gore**, who hang the stent on the aorta walls and occasionally have the devices slip out of place. That stock's pulled back almost 50% from its high, based on missing their fourth quarter. And we think that miss was more because they lost a few salespeople; then their doctors have stopped seeing the advantage of the stent. So we think that they will still grow sales this year as they hire more sales people, and that stock should react well.

Medtronic, there we see a lot of potential areas for them to grow a little bit faster between CoreValve, their new spine system, the just-released major CRT data that may go into recommendations in the next year or so. They just got their deep brain stimulation approved. We just saw the Afib data from their acquired cryo balloon that looked pretty promising. And then you add in the fact that **Boston Scientific** (BSX) has pulled all their ICDs off the U.S. market. When you combine that with the growth platforms we see coming, we think that's one to put money into.

Finally, **HeartWare**. We are, I guess, looking at the strong performance of the LVAD, or left ventricular assist device space. We think it's kind of a 20%-plus growing market or so, and we think **HeartWare** has a superior device than **Thoratec** (THOR). **Thoratec** is almost a $2 billion company, and we think **HeartWare** will take most of that market over the next four or five years and become much larger than $400 million market cap they have right now.

TWST: Are there any companies that you've rated a "sell," or that you're less optimistic about?

Dr. Lavin: The only "sell" we have is **Thoratec**, so I'm not optimistic on their competitive positioning versus **HeartWare**.

TWST: Any particular reasons?

Dr. Lavin: When you look at their data, their published six-month survival data was about 78% from their FDA trial, and it's admittedly gotten better over the last couple of years; but **HeartWare**'s European data was 90% survival at six months. And **HeartWare** has a smaller device that can be implanted in the chest instead of the abdomen, which leads to fewer infections and shorter surgical times. **HeartWare** has taken about 40% of the European market in just two quarters and just finished their U.S. trial in February. So we're expecting a U.S. launch probably a year and a half from now or so, and we think that they will take share in the U.S. very much as they take it in Europe, based on the surgical advantages that I just talked about. So I think **Thoratec** will be okay for the first quarter this year, but then I think Street numbers are pretty aggressive going forward from now.

I don't have a "sell" on **Boston Scientific**, but I do have a good amount of concern around their ICD hold and how long that's going to go on for.

TWST: What is the supply-demand balance now?

Dr. Lavin: One specific device, just overall, or?

TWST: In the medical devices sectors that you cover.

Dr. Lavin: I think hospitals cut back some of their inventories probably two to four quarters ago, so we haven't seen a big imbalance recently. It seems that after they made those cuts, that companies have seen more normalized growth. So I don't think there is at least imbalance right now unless you want to look at ICDs. I suspect that some hospitals are probably demanding new ones since they can't use one company's, but everywhere else I think supply-demand has rebalanced.

1-Year Daily Chart of HeartWare International

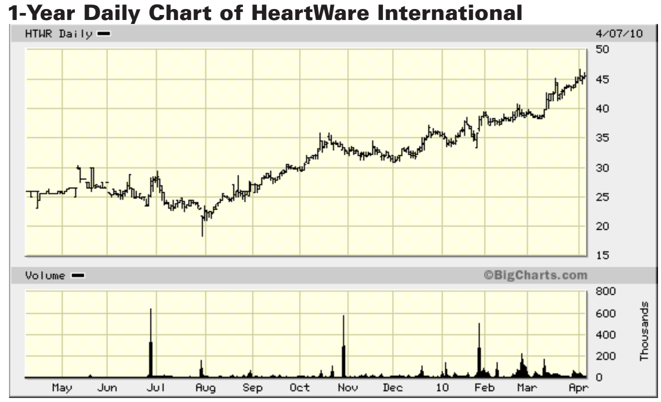

Chart provided by www.BigCharts.com

TWST: As you talk to management, what is your level of confidence at the moment?

Dr. Lavin: It varies immensely by company, but I would say it's slightly better than it was six months or 12 months ago. They're certainly seeing hospitals spend a little bit more money, and I think hospitals are more confident that they have not seen the bad debt levels some people thought they would. And they haven't seen the falloff in in-patient businesses some people thought they would with unemployment rates. So while things certainly have not been as good for hospitals in the last year as they were probably in the previous five years, I don't think it hit the low that some people thought hospitals would a year ago.

TWST: What are you advising investors to do now?

Dr. Lavin: We like the five names I had listed plus a few others. The market has obviously run a long way. So I think investors have to be a little bit pickier on where they put their money than, say, six months or year ago, but I think there is still some good buys out there. And I think if you look at companies that make surgical procedures shorter and make hospital stays shorter by being less invasive, I think those are good places to put money long term.

TWST: What is investor confidence like in this sector at the moment?

Dr. Lavin: It varies. There's certainly some people who are very bullish. Now that this health care reform is done, there is certainty there and multiples should expand some, and I probably fall into that group to some extent. And there are other people who are looking at the fact that many of the stocks I cover have run 80% or 100% in the last six to nine months, and there's a question of whether some of them will pull back some.

TWST: Do you find there are any popular beliefs or trends that may be controversial or contrary to market data?

Dr. Lavin: There's not a whole lot real controversial right now. I think six months or a year ago, health care reform was controversial, and what was going to be in it was very debated and people took different sights. But now with the bill passing, I think now people are just trying to better understand what the increase in insurance is going to do for hospitals and where they may be able to spend some more of that money. I think it's more kind of early thought process than there is controversy. I guess, maybe one place I'm a little more negative — I think there is going to be more continued push-back from hospitals on pricing of high-priced, onetime-use products than some other people believe.

TWST: What about the possibility that some consumers with chronic conditions are spending less because of the lack of health care coverage and economic recession? In the sectors that you cover, have you seen this to be case at all and does it continue to be a problem?

Dr. Lavin: I think it has happened, and I think it will continue. I don't think it has happened at rates that have really become material. So a little while, maybe a year ago, we often had people calling, concerned that patients wouldn't have cancer treated, that they would leave their prostate cancer stick around for a while because they can keep their job and not go get treatments. You know, people wouldn't take insulin because they didn't want to pay the copay on the drug. I think it happened in some. We've certainly seen some of the ophthalmology companies had a couple of rough quarters in terms of sales of glaucoma medicine and other products being destocked. I'm sure that it makes good news stories to talk about the one person who doesn't go and get the cancer treated, but I think it is a very small number of people who are putting off life-saving treatments because of the economy. And I don't think it has really showed up in the results of the companies more than a percent or two maybe in terms of growth rates.

TWST: In many cases, it may be more risks that people assess in terms of chronic conditions rather than lifesaving interventions, no?

Dr. Lavin: The area that has been hit hardest is clearly cosmetics. So the full elective procedures were hit very hard. And then there are semi-elective procedures that people maybe don't think of it as elective, but things like back pain or knee pain, hip pain, those types of things. I mean, almost every orthopedic procedure except for trauma is somewhat elective and hasn't historically really been thought of as elective. But you probably saw some of the people with minor pain who might have gone a little bit early to the hospital have put it off a little bit. So we've seen declining growth rates on, for instance, spine has grown kind of 10% to 12% for quite a while. In last quarter or so, it has been more in the 5% to 8% range. So I mean, it is certainly meaningful but not horrendous in terms of change.

TWST: And it's likely to improve as the economy does?

Dr. Lavin: Certainly as the economy gets better, those semi-elective procedures get better. And more importantly, as you have 30 million people who now have insurance, semi-elective procedures should certainly get better.

TWST: Is there anything else you would like to add as we wrap up?

Dr. Lavin: We've covered most of it. I mean, I think the one thing that remains is that, I think, most people are assuming that the Senate will pass the reconciliation changes to their original bill, and you know that's the one thing that matters. I think in terms of — most people are assuming that, and if that wasn't to go through, you have the device tax a couple of years early, and certainly feel EPS models will have to change for 2011. But assuming that goes through, I think you won't see a whole lot of change.

TWST: Thank you. (MRR)

Note: Opinions and recommendations are as of 03/23/10.

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A N A L Y S T   I N T E R V I E W

Clarifying Constraints in the Medical Device Space

BROOKS WEST — CRAIG-HALLUM CAPITAL GROUP LLC

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SECTOR — MEDICAL DEVICES

(ABF805) TWST: How do you think, if at all, the universe you cover has been affected by the economy and the passage of health care reform?

Mr. West: Let me do the health care bill first. I think that "A," for the med tech stocks, it's nice to have finality in terms of what the bill is going to look like versus having to debate what a bill might look like and the impact to medical devices really over the past year. So it's nice to have it done. Two, I think it is a net positive for the device business near term. And looking out into 2013, when the tax starts to hit, obviously that's something that will need to be offset. My bigger worry is actually the changes that are going on at FDA, and maybe that's a separate conversation. But near term, I say the bill is a net positive for the stocks. You know, switching back to the impact to the economy, obviously we saw a slowdown last year across the board — procedures, hospital spending — and that had a wide-ranging negative effect on the med tech industry. I think that we've seen stabilization and maybe pockets of improvement, but it's hard to point to an ongoing trend at this point. But we are certainly glad to have last year over.

TWST: You mentioned the FDA. What specifically are you referring to when you referenced it as a concern?

Mr. West: My biggest concern, and this ties into the macro theme that we are working on right now with our clients, I think you have large companies — we cover a range of large and small cap, but particularly the large companies — thinking about how to offset the tax that's going to happen in 2013. The FDA on top of that has gotten very tight in its approval process, and it looks like the 510(k) approval pathway is in a serious jeopardy. So you net that out, it's going to get very, very difficult for companies large and small to get things approved. There is going to be more clinical data that's going to need to be generated, that implies longer time frames and more spending. So we see a scenario going forward where there is going to be a necessary consolidation within the medical device space and perhaps, even looking at a **J&J** (JNJ) or an **Abbott** (ABT), consolidation of device and pharma biotech, as large companies look to "A," acquire growth and "B," offset increased, basically expenses to do with both the FDA and the pending tax. So we are telling clients to focus on small- and mid-cap companies with basically three characteristics: defensible or dominant niche franchises, and then growth and margin structures that would be accretive to a large acquirer.

> **Highlights**
>
> *Brooks West provides an overview of the medical device space and the companies he covers, highlighting their research and development efforts. He expects increased consolidation, advising investors to watch small- and mid-cap companies that may be swallowed by this trend. Mr. West also outlines several factors affecting the space at the moment, including FDA restrictions and the associated costs of developing new products, as the biggest issues facing the industry. He says the finality of health care reform has been a positive for stocks. Companies include: Johnson & Johnson (JNJ); Abbott Laboratories (ABT); American Medical Systems Holdings (AMMD); NuVasive (NUVA); Arthrocare (ARTC); AngioDynamics (ANGO); Boston Scientific (BSX); St. Jude Medical (STJ); Edwards Lifesciences (EW) and Medtronic (MDT).*

TWST: What are your top stock picks at the moment?

Mr. West: In keeping with our thought process, we like **American Medical Systems** (AMMD), we like **NuVasive** (NUVA), we like **ArthroCare** (ARTC) and as more of an almost special situations play, we like a company called **AngioDynamics** (ANGO).

TWST: Are there any stocks at the moment that you are not as enthusiastic about or that you have a "sell" rating on?

Mr. West: I don't have a "sell" on anything at the moment, but we've gone to a "hold" on the big cardio space. So we follow **Boston Scientific** (BSX), **St. Jude** (STJ), **Edwards** (EW). I think the CRM space is slowing down. The stent space is clearly at a flat or a negative growth trajectory. And so I don't see those companies commanding the same multiples that they did in the past. And while we love **Edwards**, we just think it's too expensive at its current price.

TWST: As you talk to management, what are their concerns right now?

Mr. West: I think it's mainly around FDA and the tightening at FDA. I think that's going to be a theme that is going to play out more and more over the next year, and I think FDA looks to become more and more conservative. And that has implications for new product approvals, even situations like **Boston Scientific** is currently in, where you might have a misstep with FDA. I think the agency is just getting tougher and tougher. I think secondarily to that would just be probably FX and a slower European turnaround. So Europe is definitely lagging the U.S., and obviously everybody is looking for a return to a more robust U.S. economy so we can see procedure volumes, especially elective procedure volumes, return to a more normal pace.

"Setting aside the very big companies, we like the R&D teams at St. Jude and Edwards and the like. I continue to be impressed by the renewed R&D effort at American Medical and also at NuVasive."

TWST: You discussed this a bit, trends that you like to see. Are there any companies right now that are developing products that you think will give their stocks a push?

Mr. West: I mean, you look at a company like **AngioDynamics**, which I mentioned. The base business is kind of slow and steady; they have a technology called irreversible electroporation. Their commercial product is called NanoKnife, which is a solid tumor cancer therapy. It's basically a nonthermal ablation device, and it's one of the best things I've seen come out of the device world in many years. I think that's a situation where you could actually have a product. It's got 510(k) approval, general soft tissue approval in the United States, and it's got a CE Mark. They are building clinical data for specific cancer indications, but that could really be a game-changing technology. There are very few things, I mean, obviously the transcatheter valves, so there is a reason that it is as expensive as it is. But there are very few kind of big ideas out there in public medial device that are stand-alone companies.

TWST: Are there any ideas that are slotted as bigger than they really are at the moment?

Mr. West: As much as we like **Edwards**, we look at **Edwards**' Sapien program, and we see a value that's probably two times what **Medtronic** (MDT) paid to get into the space. So **Medtronic** bought a company called **Ventor** and a company called **CoreValve**. I think that **EW** is probably a bit stretched in terms of valuation. In terms of other clinical ideas, I think people are still trying to figure out the stroke market. I don't know if there is a great play there and obviously the AFib market remains a robust opportunity, which just is — the clinical proof is trailing probably the market development by several years.

TWST: What conversations are you having with investors at the moment, and what are their concerns?

Mr. West: I think investors at the moment are viewing — there is no longer a drastic discount to the medical device stocks by and large. So the easy play of "buy a down industry and watch it correct back" is probably over. Investors are looking for specific ideas now. I think again, people are worried about FX and its impact on the device space. Then I am just echoing what I said earlier about FDA and industry consolidation.

TWST: What are you advising them to do now?

Mr. West: We are pushing this idea hard of small- and mid-cap ideas, like I outlined earlier, that you could view as great stand-alone companies that you want to own and also likely consolidation candidates.

TWST: Are there any companies that have a really strong R&D team?

Mr. West: Setting aside the very big companies, we like the R&D teams at **St. Jude** and **Edwards** and the like. I continue to be impressed by the renewed R&D effort at **American Medical** and also at **NuVasive**.

1-Year Daily Chart of Edwards Lifesciences

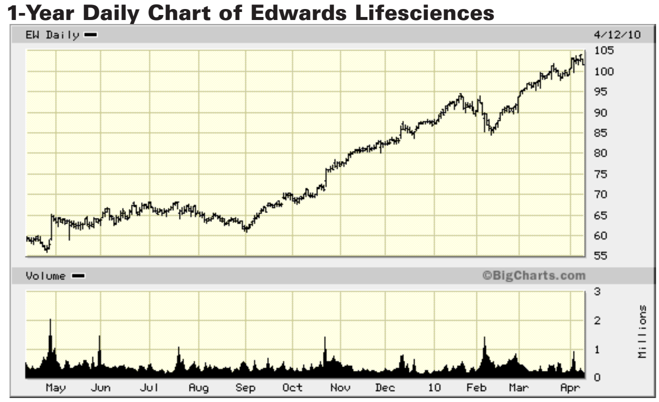

Chart provided by www.BigCharts.com

TWST: I haven't heard the FDA come up much in my other interviews. Are there any other points on which you or your group take a more contrarian stance to the main zeitgeist?

Mr. West: FDA has been quite clear. And you know, being here in Minneapolis, with the medical device community that we have, I think there are over 500 medical device companies between University of Minnesota and Mayo Clinic, constituting one of the largest clusters in the world. There is a huge concern within the, not only the R&D community, but the venture capital community, all the way up to the CEO of **Medtronic**, who are looking at the associated cost with developing new products, especially if the 510(k) pathway is tightened or eliminated. It's going to tack on multiple years to the development process, and it's going to cause hundreds and millions of dollars of extra money to get especially Class III data. So I think that's the biggest issue facing the industry right now — it's not the health care bill, it's FDA. And so you know, you can say that's maybe a contrarian view. We see any company that is reliant on R&D pipeline conversions, especially for a significant new product, I think you have to discount not only the timeline but also the associated dollars looking forward. On the other hand, companies who have gotten new technologies through the agency stand to benefit.

TWST: Thank you. (MRR)

Note: Opinions and recommendations are as of 03/24/10.

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J U N A I D   H U S A I N — S O L E I L   S E C U R I T I E S   G R O U P ,   I N C .

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SECTOR — HEALTH SERVICES

(ABF810) TWST: I was wondering how your coverage universe has changed, if at all, since the last time you spoke with us in January?

Mr. Husain: No, it hasn't. The coverage universe is still the same. I cover medical technology, which is a pretty broad space. And within medical technology, I cover three buckets of stocks. I cover diversified medical supplies, which would include names such as **Baxter** (BAX), **Hospira** (HSP), **ICU Medical** (ICUI) and **Mindray** (MR). And then I follow capital equipment. And within capital equipment, I've got the radiation oncology vendors, such as **Accuray** (ARAY), **TomoTherapy** (TOMO) and **Varian Medical Systems** (VAR). Within that capital equipment bucket, you also have **Intuitive Surgical** (ISRG) and **Hologic** (HOLX). And then the last bucket is diagnostics. And within diagnostics, I cover names like **Sequenom** (SQNM), **Bio-Rad Laboratiores** (BIO), **Myriad Genetics** (MYGN) and a little micro-cap company called **SenoRx** (SENO).

Highlights

Analyst Junaid Husain discusses his coverage of the medical devices industry, offering both bullish and bearish takes on the long- and short-term effects of health care reform. Mr Husain highlights his favorite stock picks and discusses the plasma products industry.

Companies include: Baxter International (BAX); Hospira (HSP); ICU Medical (ICUI); Mindray Medical International Limited (MR); Accuray (ARAY); TomoTherapy (TOMO); Varian Medical Systems (VAR); Intuitive Surgical (ISRG); Hologic (HOLX); Sequenom (SQNM); Bio-Rad Laboratories (BIO); Myriad Genetics (MYGN); SenoRx (SENO); Abbott Laboratories (ABT); Talecris Biotherapeutics Holdings (TLCR) and Grifols (GRF.MC).

TWST: What do these various segments look like at the moment? Might they benefit from health care reform? If not now, then in the future?

Mr. Husain: Well, health care reform and its impact to the medical technology space is still somewhat of an unknown. I guess the bull case on health care reform is that you're going to have, call it whatever, 30 million or 40 million additional Americans that are going to get health care coverage, and because they're going to get health care coverage, they will need to see their doctors. They'll need to do visits to their hospitals, and they will require medical technologies. And so there should be greater utilization of all of these health care services and all of the associated medical technologies. So the presumption then is that over the course of the next, call it, five to 10 years, medical technology companies should benefit. The bear case on health care reform relative to medical technology is the provision within the legislation that has many of the med tech companies a little bent out of shape, and that has to do with the medical device tax. The medical device tax — call it a 2.3% excise tax — will begin in 2013. Roughly $20 billion could be collected in total from the med tech companies on

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the basis of this tax. The problem is that there's not going to be any guardrail or cap on this tax. So the presumption is that this device tax could potentially go higher. So that's the bull and the bear case for health care reform as it pertains to medical technology. At the end of the day, it could have been far worse. Certainly some of the health care proposals that were floated around were calling for a device tax that would reap something to the tune of $40 billion in total, again with no cap. So it's been pared back a bit. But still for an industry which generates, call it, roughly $100 billion to $150 billion per year, a device tax like this is still fairly substantial. And for an industry that consists of a lot of small to medium-sized companies, a 2% to 3% device tax, especially for companies that are just turning the corner on profitability, can negatively impact their fledgling business. I think that's my take on health care reform in general — short-term impact, not too significant. But we could certainly see a long-term impact on the industry.

"When I talk to hospital administrators, the sense that I get is that things have stabilized and for some hospitals things are getting better."

1-Year Daily Chart of Varian Medical Systems

Chart provided by www.BigCharts.com

TWST: What about the economy? Do you believe the economic situation is improving at all and will positively affect your coverage universe? How do you see that playing out?

Mr. Husain: I think that we're certainly at a different place now than we were, say, a year ago. When I talk to hospital administrators, the sense that I get is that things have stabilized and for some hospitals things are getting better. As you know, I cover a lot of capital equipment companies. And for hospitals that were tightening the purse strings on the capital equipment front, these institutions might be willing to have cap ex conversations. But capital equipment is still in a very sensitive place right now. If hospitals are going to open up the purse strings for a $1 million robot or a $2 million to $3 million linear accelerator for radiation oncology, they need to make sure that they're going to get a good bang for their buck. They need to make sure that they're going to see a return. Consider, for example, the da Vinci System from **Intuitive Surgical**. **Intuitive Surgical** has put up fantastic quarters. Even last year, in the midst of a very difficult environment, **Intuitive Surgical** was crushing numbers; they were beating my estimates and I was the high man on the Street. They were beating the Street on revenues, on box placements and on the earnings line as well. And I think that's a function of the fact that hospitals look at robotic surgery as a way to drive patient volume. Patient volume at hospitals is the name of the game. And if you've got a technology that is really cool looking, really cool sounding, and you can splash around on your marketing brochures, then that could potentially be a win for a hospital. Again, hospitals are all about patient volumes, and so I think if you can make investments in capital equipment that drive patient volumes, that's a win. So that's kind of a roundabout way of saying that things are getting somewhat better for hospitals. Hospitals are certainly being more disciplined with their cash and making investments where they think they can get a big return on investment.

TWST: What are your top stock picks at the moment?

Mr. Husain: My favorite pick in my medical technology universe is in fact a capital equipment play; it's **Varian Medical Systems**, ticker VAR. It is a "buy"-rated stock in my universe. And I like **Varian** for a bunch of reasons. **Varian** is looking to make a big splash in the next few weeks with a major new product introduction, and this is for a next-generation radiation oncology instrument. And radiation oncology really hasn't changed too much in last 30 or 40 years. What this means is that these radiation oncology boxes are using technologies that were developed in the late 1960s, early 1970s. It's clunky technology that needs to advance, and so **Varian** has made a lot of significant changes in its core linear accelerator technology. And these are changes that are not cosmetic but are really fundamental. It's going to make the radiation oncology box more efficient, more streamlined, more user-friendly for medical physicists and radiation oncologists to use. But more importantly, it's going to enable **Varian** to tap into a very key and lucrative market in whole-body stereotactic radiosurgery. Back in 2007-2008, **Varian** introduced an efficiency software called RapidArc, which made radiation oncology treatments very, very efficient. Hospitals, as you probably remember back in 2007-2008, were starting to feel it on the financial front and were becoming more disciplined with their cash. Hospitals were looking for ways to get a bigger bang for their cap ex bucks. This was essentially why RapidArc was so very compelling for hospitals. And in a similar vein, **Varian** is looking to launch this new radiation oncology instrument with the same idea. They're continuing on this theme of speed and being able to administer radiation to patients in a much more efficient manner. Essentially the thought process is, "Can we make radiation oncology better, faster, cheaper? Can we provide a product for hospital customers where they should be able to maximize their return on investment?" Radiation oncology for hospitals is one of the last great profit centers. And so as hospitals look at health care reforms, especially as they are on the hook for $155 billion in reimbursement concessions over the next 10 years, they need to be smart about cash deployment and what they can get a big return on. Radiation oncology is the one of those areas where they can get a good return on by purchasing **Varian** equipment. So it's a win of an investment for a hospital, and I see good prospects for **Varian** with this new box. Relative to **Varian** as an investment, the stock is trading at about 18.5 times forward numbers. And what we've known historically from **Varian**, when **Varian** has a new product rollout, the multiples start to expand, and they usually expand in the low to mid 20s. So with the stock at 18.5 times, there's a lot of valuation runway left here. So that's one of the key reasons why **Varian** is my top pick in med tech for 2010.

"Technology is an enabler, and it is one of the reasons why companies can perform. It's the innovation engine that drives stock price performance."

1-Year Daily Chart of Myriad Genetics

Chart provided by www.BigCharts.com

TWST: Are there any stocks you have a "sell" on at the moment?

Mr. Husain: I do. Continuing on this theme of capital equipment and radiation oncology, the pair trade that I see in radiation oncology is with **Accuray**. So go long **Varian** and go short **Accuray**. So I changed my opinion on **Accuray** recently. I downgraded them to a "sell." And the reason I did that is because I see this new radiation oncology machine from **Varian** being a major competitive threat to **Accuray**. And the reason why I say that is because **Accuray**'s bread-and-butter business is selling these stereotactic radiosurgery boxes. And this is exactly the place that **Varian** wants to play in. And so when you've got **Varian**, as the 800-pound gorilla in radiation oncology, saying that they what to play in your market, then this could potentially be a problem for **Accuray**. **Accuray** was able to capture a niche for itself in the radiation oncology market primarily by catering to neurosurgeons. But they've been looking to expand their footprint to tap into markets that **Varian** has been playing in. **Varian** doesn't really play in a lot of the neurosurgical applications, and they want to have a bigger presence amongst the neurosurgery community. So I see this new radiation oncology box being very competitive against the likes of **Accuray**'s CyberKnife system. Ultimately, I think **Accuray** is in for a tough time over the next year, year and a half, as **Varian** rolls this new product out.

TWST: As you talk to management teams across the sectors you cover, what is their level of confidence?

Mr. Husain: I think that speaking to CEOs and CFOs over the last couple of months, my sense is that things are picking up. I think that there is cautious optimism that 2010 will be a better year than 2009. Certainly coming out of Q1 earnings, all of the companies reported reasonably good quarters. It was mostly "hit the quarter or beat the quarter" within my coverage universe. And I think from a guidance perspective, a lot of companies were playing it safe and were conservative out the gate for 2010. Management guidance was either within Wall Street's range or maybe slightly below Wall Street's range. But I suspect that numbers will start creeping upwards as we head into the next few quarters.

TWST: How are you advising investors at the moment?

Mr. Husain: Well, I think that within the different buckets of medical technology, I think there are good opportunities to invest in some great companies that are making good investments in technology. Technology is an enabler, and it is one of the reasons why companies can perform. It's the innovation engine that drives stock price performance. And so within my coverage universe, I think those companies that can make those investments in R&D and can quickly convert innovation into new products sooner versus later will be the winners. And so within that broad mandate and relative to the different buckets of my medical technology coverage universe, I see a bunch of winners. Within capital equipment, we've already talked about **Varian**. Within the diagnostics space, it would be a company like **Myriad Genetics**. **Myriad Genetics**, ticker MYGN, it is a "buy"-rated stock in my universe. **Myriad** is the kind of company that has been a one-trick pony for probably 10 years or so. 80% of its business is this breast cancer test called BRACAnalysis, and BRAC has had a strong grower. It consistently has grown in the 15% to 20% range year-over-year. But there is the sense that **Myriad Genetics** needs to develop other tests. And they are starting to do just that in order to potentially fill any revenue gaps, especially as BRAC starts to mature. There is a real sense that Myraid needs to begin monetizing its R&D engine to produce additional products, and I'm hopeful that **Myriad Genetics** is up to task. They have launched three products over the last three years in next-generation molecular diagnostic tests; tests that are not just these yes/no diagnostics, but rather tests that provide information that enables clinicians to make better medical decisions. Whether its personalized medicine, or prognostics or theranostics, it's what you do with this information that provides clinicians value. Consider personalized medicine diagnostics, for example, as it relates to providing better pharmaceutical decision-making. This is a concept that I'd like to refer to as "Dx on the R," using diagnostic information to better inform pharmaceutical decision-making processes. And that's a hot area in diagnostics, and its a hot area for a lot of pharmaceutical companies. And again, this is exactly the type of innovation that I'd like to see. And this is exactly the type of innovation that a lot of the large pharmaceutical companies like to see. So I imagine that these next-generation diagnostic tests from companies, like **Myriad Genetics**, will enable them to take their business to the next level. And that's why I have **Myriad Genetics** at a "buy."

And then the last bucket within my coverage universe, in the diversified medical supply space, one of my favorite names in that space is **Hospira**, ticker HSP. It's a "buy"-rated stock in my universe. And **Hospira** has had a fantastic run. I've covered **Hospira** since they spun out of **Abbott Laboratories** (ABT) back in 2004. So I've known this company and this management team for six years. And **Hospira** is a very different company now than it was back in 2004. Back in 2004, it was this stodgy, old-school medical supplies company that produced an amalgam of different products in a bunch of different spaces — critical care products, infusion pumps, tubes, connectors. A lot of these products that were low margin and really not growing at significant rates, so maybe market growth rate, 3%, 4%, tops 5%. And since 2004, the company has really transformed itself. The company is less of a med tech company now and more of a specialty generics company. And they've made a big acquisition back in 2007 with a company called **Mayne Pharmaceuticals**. **Mayne** is an Australian specialty pharmaceuticals company. 70% of **Mayne Pharmaceuticals**' products are oncology drugs. And **Hospira** has been becoming, what I'd like to refer to as an edgier company, so to speak. They are comfortable making risky R&D bets in certain therapeutic areas. So for example, last year they made a big bet on a cancer drug called Oxaliplatin. And they launched this drug at risk, meaning that they launched the drug when the patent litigation was still going on. And they were able to overcome many of the legal issues associated with this product, and they launched at risk. And by launching at risk, they were able to secure a significant amount of market share and revenue. In fact, it was one of the key reasons why they crushed expectations, and it's one of the reasons why the stock has done so well. In 2010 that edginess to **Hospira** will continue, as they look to launch a bunch of products in various geographies. So I think that this company has undergone a fantastic transformation. And again, it points to this theme of smart R&D and extending yourself beyond your comfort zone, which makes for a well-performing company.

"And Hospira has been becoming, what I'd like to refer to as an edgier company, so to speak. They are comfortable making risky R&D bets in certain therapeutic areas."

TWST: What is investor interest like in the space at the moment? Does it match your own enthusiasm?

Mr. Husain: It's interesting you say that because my sense is that investors have looked at some of these companies, whether it's **Varian**, **Hospira** or **Myriad Genetics**, with a little bit of suspicion. If you look at the 52-week charts for a lot of these companies in the med tech space, they've all had fantastic runs since last year. So I think a lot of investors are looking at these charts, looking at what the S&P is doing and thinking to themselves, "I've made some fantastic gains here. I think I'm going to lock in my gains and then head to the sidelines right now, and see how all of this plays out." As we come out of Q1, my sense was that it was a good quarter, but it's the Q2 earnings report that going to be the defining moment, the inflection point, if you will. Q2 results will essentially answer the fundamental question, "Is the economic recovery real or illusory?" Broadly speaking, I think most investors did breathe a sigh of relief after the health care reform bill was passed. And whether or not you view the outcome as good or bad for health care stocks, I think most investors were just relieved that that the overhang was removed. So it's interesting how my conversations with investors has evolved. Clients are more inquisitive about particular stocks versus the larger, macro picture. There is still some caution out there, gut I think investors are hopeful that the recovery is real. And I think investors are hopeful that health care reform is mostly behind us now, and it is not going to have too material of an impact on medical technology stocks.

1-Year Daily Chart of Hospira

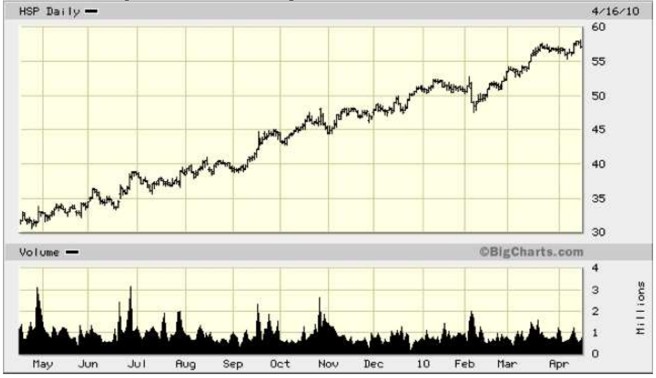

Chart provided by www.BigCharts.com

TWST: As you look at the space and hear commentary from other analysts, investors or management, is there something that you feel many are getting wrong? Do you have a maverick position, so to speak?

Mr. Husain: If there is a maverick position that I have, it would be relative to diversified medical supplies and relative to the space for plasma products. So the plasma product industry is about an $8 billion industry, so it's an industry that a bunch of large, integrated companies — companies like **Baxter** International, Australian-based **CSL**, a relatively new publicly traded company **Talecris Biotherapeutics** (TLCR), and then the Spanish company **Grifols** (GRF.MC) and then another privately-held European company **Octapharma** — so these five companies plus a handful of smaller companies play in the $8 billion market for plasma therapies. And half of this market is comprised of this one plasma fraction called IVIG, or intravenous immunoglobulin. I have been the contrarian — or maverick, as you call it — on this market. I've been the contrarian because of some of the things that I see going on in the overall market. IVIG is a very expensive drug therapy that's used for a variety of different clinical indications — things such as primary immunodeficiency disease, Guillain-Barré syndrome and CIDP, Chronic Inflammatory Demyelinating Polyneuropathy. So essentially it's a drug therapy that's used in a miscellany of different clinical indications for the treatment of the patients that are immunocompromised. This market has been growing nicely over the last, call it, three or four years, with fantastic price increases and solid demand. Three years ago, pricing was sitting at about $50 to $55 per gram, and now it's somewhere between $70 to $75 per gram. And demand has been fairly steady, with demand growing anywhere from 5% to 10% year-over-year. So it's a very sought-after drug therapy by clinicians. Now what we saw happening early last year, with IVIG's pricing sitting north of $75 per gram, there was a lot of angst amongst payers. Payers were getting kicked in the gut having to reimburse for a very expensive drug therapy. So it was a combination of the payers and a difficult economy that made some argue for alternative drug therapies instead of very pricey IVIG. And what we started to notice is that IVIG usage started to pare back. So not only did IVIG volume start to soften, but pricing also started to soften in the beginning of 2009. So my thesis on this space is that pricing will continue to be soft and demand will be sluggish, and this is somewhat of a challenge for the plasma business. The plasma business is a fully integrated business; you have companies that do plasma collections, they do the fractionation, and they do the distribution. This is a high fixed-cost business, and it's very much dependent on the vagaries of the IVIG market. And if the IVIG market is getting soft, then this market is in for some uncertain times. And so my thesis on IVIG has been that for 2010, we're going to have flat to possibly down pricing, and demand that could be flattish or in negative territory. And I think that could be somewhat challenging for all of plasma companies. For companies like **Baxter** International, which is a "hold"-rated stock in my universe, I think they should be able to weather the storm. They're mostly on long-term contracts for IVIG; pricing is already locked in for 2010. But I think for companies like **Talecris**, which generate something to like 55% to 60% of their total revenues from this one product, IVIG in the U.S., I think they could be in for a bit more uncertainty over the next six to 12 months, as the IVIG market gets softer. The plasma manufacturers have said they continue to think that while pricing might be flat to low single digits, demand should still be in the 6%-plus range year-over-year. I don't really agree with that assumption. I'm not so sure how they'll be able to maintain demand at the 6% level. And in fact, if it goes lower than 6%, then I think we could see some risks to numbers, especially for a company like **Talecris**, that is so levered to IVIG in the U.S. So it remains to be seen how this thesis plays out. But I certainly have been the contrarian on IVIG, and I've been right.

TWST: Thank you. (MRR)

Note: Opinions and recommendations are as of 03/24/10.

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Medical Device Companies Advance With Changing Tide

JOANNE K. WUENSCH — BMO CAPITAL MARKETS CORP.

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SECTOR — MEDICAL DEVICES

(ABF806) TWST: What are the major trends in the medical devices industry at the moment?

Ms. Wuensch: There are several. Over the last year the focus for many investors has been health care reform, and while that is largely behind us, there are lingering questions. In addition, pricing, industry consolidation, new product pipelines and potential market share shifts are ongoing trends.

TWST: Which of these will have the most impact? Do you think it will be health care reform, consolidation or something else?

Ms. Wuensch: For the stocks, it is probably consolidation. For the industry, I could argue that both health care reform and consolidation over the next several years will be impactful. The good news is that we know that it is a 2.3% excise tax that will begin impacting the medical technology companies in 2013. With this knowledge, I think it is easier for organizations to value potential acquisitions and plan for the future. In 2009 there were 23 M&A transactions above $68 million, with only two above $1 billion. This compares to 2007, when there were 40 transactions, with 12 above $1 billion. Looking over the next 12 months to 18 months, we believe that the industry is prime for consolidation.

Highlights

Joanne K. Wuensch discusses her favorite medical device companies, which have acquired enough cash on their balance sheets to benefit from purchasing fast-growing technologies. She lists Covidien, Medtronic and Abbott Laboratories as leaders in consolidation trends, citing NuVasive s spine surgery technology as the reason behind the company s double-digit revenue growth rates. With health care reform established and preparation for the med tech tax beginning, Ms. Wuensch predicts increased M&A activity in the next 12 months.

Companies include: Covidien (COV); C.R. Bard (BCR); Medtronic (MDT); Johnson & Johnson (JNJ); Abbott Laboratories (ABT); Stryker (SYK); Zimmer Holdings (ZMH); St. Jude Medical (STJ) and NuVasive (NUVA).

TWST: What stocks will benefit the most over the next several years? Which are in good shape to take advantage of the sway of the tide at the moment?

Ms. Wuensch: There are several ways to answer this. On a fundamental basis, we anticipate that hospital supply companies **Covidien** (COV), **C.R. Bard** (BCR) will benefit from the increased patient flow starting in 2014. From a consolidator point of view, companies such as **Medtronic** (MDT), **Johnson & Johnson** (JNJ), **Abbott Laboratories** (ABT), **Covidien**, **Stryker** (SYK), **Zimmer** (ZMH) and **St. Jude Medical** (STJ) have a fair amount of cash on their balance sheet and could benefit from purchasing faster-growing technologies. Finally, the smaller companies and their stocks could benefit. From my list, I've got a long list of possible acquirees. Some of this has already begun. In the last 12 months to 18 months, **Covidien** purchased **VNUS Medical**; **Medtronic** purchased **Invatec** and **CoreValve**; and **Abbott** purchased **Advanced Medical Optics**. But we believe that with health care reform well understood, large-cap multiples recovering and cash on the balance sheet, there will be more sooner rather than later.

TWST: What are the strongest stocks now?

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Ms. Wuensch: Strongest in what way?

TWST: The best stock picks.

Ms. Wuensch: I think that **Covidien** is in a great position. The company, which has been publicly traded since June 2007, has been executing its strategic plan. Management has sold off noncore, lower-margin businesses, purchased adjacent, higher-margin businesses, and invested in research and development to drive higher operating margins. In addition, management has managed the company's debt burden, tax rate and cash flow. For the stock to work, continued leverage of the P&L, which should drive top-line growth and bottom-line returns, should do the trick.

Stryker is another one. The stock should benefit from a recovering orthopaedic market, a recovering hospital purchasing environment — the MedSurg business is roughly 40% of sales — and an easing regulatory environment. Two of the company's four FDA warning letters have been lifted. Further, the company has almost $4 billion in cash on the balance sheet.

Finally, I would point to **NuVasive** (NUVA). With reimbursement questions behind it, the company management has guided to 30% to 35% revenue growth in 2010, as it continues its momentum in the U.S. with the introduction of lateral access spine surgery. And management is just beginning to push outside of the United States. Further, the technology is well positioned in the current health care economic environment, as the procedure lowers operating room time, the number of hospital days and returns patients to their normal activities faster.

TWST: How is the economy affecting the industry at the moment?

Ms. Wuensch: At the moment, the industry is in a recovery mode. At the first light of the economic downturn, we witnessed a slowdown in breast augmentations, lap-band procedures and laser vision correction — things that are truly elective. The secondary items were items that are not so elective but can be considered elective for now, such as hips and knee procedures. During a very brief period, items that we never thought of as elective were impacted, items such as glaucoma eye drops. In the recovery mode, we are beginning to see a return of the hip and knee procedures but have not returned quite yet to the truly elective procedures, such as laser vision correction.

TWST: What do you see in terms of capital spending on the other end, the hospital end?

Ms. Wuensch: At the hospital end, some of the capital purchasing delays are somewhat temporary; you can't put them off forever. Many hospitals received a dual hit last year — the economy and the uncertainty associated with health care reform. It appears that the environment is improving somewhat, although with a long tail, as economic recovery and clarification on health care reform should revive spending. Now what they choose to spend on first is still to be seen.

TWST: Are there any stocks at the moment that you see as particularly weak or that you have a "sell" rating on?

Ms. Wuensch: I don't have any under "underperform" ratings on my coverage list at this stage, as I believe that med tech valuations are still low compared to historical averages and the industry growth rates.

TWST: As you talk to management at the moment, what's their level of confidence?

Ms. Wuensch: Which management?

TWST: Just generally, management of the companies that you cover.

Ms. Wuensch: I think in general, they are feeling better this year than a year ago. It was just last March when health care reform hit the tape, and companies as well investors scrambled to understand the pending changes. In some ways, it was a perfect storm — managing a weak economy while preparing for health care reform. Fast-forward a year, the economy is better, we know what we're doing with health care reform and decisions can be made how to manage the med tech tax. So I do think that managements are in a better spot, which is part of the reason we anticipate more M&A in the next 12 months than the last 12 months.

TWST: What is investor interest like at the moment?

Ms. Wuensch: Exiting the fourth quarter of last year, I started to see a pickup in interest in the group, not just from the health care specialists but definitely from the generalists, which is reflected in the stock multiples today versus last September and October. Further, I anticipate that the level of interest will continue, as we move back to industry fundamentals and away from economic and health care reform concerns.

TWST: What are you advising investors to do now?

Ms. Wuensch: We have an "outperform" rating on the group. We upgraded the med tech sector last fall, on September 18, to "outperform" from "market perform." And we have maintained the rating. Every investor is different. Some are looking for turnaround names, others for acquisition candidates, and some are looking at fundamental industry and market share shifts. Our conversations with investors have covered these three themes, while understanding their appetite for risk and market cap preferences.

TWST: Thank you. (MRR)

Note: Opinions and recommendations are as of 03/22/10.

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For disclosure please see http://researchglobal.bmocapitalmarkets.com/Company_Disclosure_Public.asp?nl=Y.

Medical Device Industry On Guard

JEFF JONAS GABELLI & COMPANY, INC.

JEFF JONAS joined Gabelli & Company, Inc., as an Analyst in July 2003, expanding the firm s coverage of the medical device sector. He has focused on companies in the cardiovascular, plastic surgery and pharmacy benefits management sectors, among others. Mr. Jonas was a Co-Portfolio Manager of the GAMCO Medical Opportunities partnership from January 2006 until July 2007 and has since served as Co-Portfolio Manager of the Gabelli Healthcare and Wellness Trust. He was a Presidential Scholar at Boston College, where he graduated from the Carroll School of Management with a B.S. in finance and management information systems.

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SECTOR — MEDICAL DEVICES

(ABF807) TWST: How has the medical device landscape changed since we last spoke in September 2009?

Mr. Jonas: I think it's gotten a little bit more difficult. There's been more price pressure, especially across some of the cardiovascular devices, like drug-eluting stents and to a lesser extent pacemakers and defibrillators. Last time we spoke was about six months ago, when **Boston Scientific** (BSX) looked like they were really getting their act together, with a new CEO and a couple of good quarters behind them. And now they run into these challenges of price pressure across their businesses, the loss of some key employees and another round of issues with the FDA. While a lot of that is specific to them, I also think some of it is kind of symptomatic of how the environment is more difficult now.

TWST: What factors are making the environment more difficult? Health care reform has been pushed through — do you foresee challenges on that front? Or is it more so the economy and/or the FDA?

Mr. Jonas: It's really all three of them. Health care reform, I think, is mostly neutral for the medical device industry. There is the excise tax, 2.3%, that starts in 2013, but I think they will be able to manage through that. It is tax deductible. It's possible they will be able to raise prices a little bit to offset that, although it's far from clear. And then I think companies will be able to operate more efficiently, cut some discretionary and other spending to offset that. But I think the FDA has gotten more difficult, and they've been pretty high profile, clamping down on the 510(k) process, demanding more data, oftentimes demanding superiority data. Timelines for product approvals have stretched out a bit longer. Then some of the price pressure is coming from hospitals as well. They are seeing more uninsured and charity cases, so their financial health is not as great. And they are asking for discounts from a lot of the medical devices companies to help deal with that.

Highlights

Jeff Jonas outlines the hurdles facing the medical device sector, namely health care reform, the FDA and the economy. He underlines St. Jude as a top stock pick, citing the company's fast-growing portfolio of new products. Mr. Jonas says both industry managers and investors are cautious on the space, and he warns investors to keep their eyes on specific stocks, those that are experiencing growth and have the most to gain from health care reform.

Companies include: Boston Scientific (BSX); St. Jude Medical (STJ); Edwards Lifesciences (EW); Genoptix (GXDX); Kinetic Concepts (KCI) and Smith & Nephew (SNN).

TWST: What are some strong stock picks at the moment and why?

Mr. Jonas: I think **St. Jude** (STJ) is going to emerge as a winner from all of this. They'll benefit from some of the problems that **Boston Scientific** is going through. They will gain some share in pacemakers and defibrillators just because they are such a reliable supplier with a range of new products that are coming to market. So I think they'll benefit from **Boston Scientific** being off the market and hiring away certain key employees. **St. Jude**'s business is just so well positioned on its own now. They've got great product platforms in neuromodulation and atrial fibrillation. And now they are starting to build up their cardiovascular division with guidewires, heart valves, the new pressure wire that can help determine if you need stents or not. They've got one of the fastest organically growing portfolios of the large-cap medical device companies.

TWST: At the moment, are there any companies you

perceive as weak or that you have a "sell" rating on?

Mr. Jonas: We've already covered **Boston Scientific**, and they have a lot of issues that will take a significant amount of time to resolve. I think **Edwards Lifesciences** (EW) is just trading at an extremely high multiple right now, 15 times EBITDA and almost 30 times earnings. I just don't see any upside left in the stock at this point. I think the potential for percutaneous heart valves is huge. They've proven that in Europe, and they will be in the U.S. in the next couple of years. But at the current valuation, I just don't see what upside is left for the stock. And if there are any delays or any snags along the way to U.S. approval, there certainly could be a lot of downside. So that's one name that we've been avoiding recently.

"Health care reform, I think, is mostly neutral for the medical device industry. There is the excise tax, 2.3%, that starts in 2013, but I think they will be able to manage through that."

TWST: You discussed several specific products, but is there any company whose product addresses an unmet need and could unexpectedly drive growth in the next few quarters?

Mr. Jonas: I think one company that has great growth is **Genoptix** (GXDX). They are a diagnostic testing company for blood-based cancers, like leukemia. They've got a central lab in California that they are expanding to run all of their tests. And they just continue to put up very good growth of 30% or 40% on the top line per year. They only cover about half of the country so far, so they are hiring sales people and increasing their marketing efforts to reach to the whole country. And now they are starting to test for new types of cancer as well. Colorectal cancer is another type that responds well to genetic tests, where you can guide what drug and what therapy is best. They are starting to acquire and license proprietary tests as well. I expect them to continue to grow very rapidly and the management team has always been extremely conservative in their guidance. So I think there is certainly the possibility of some upside in the next few quarters.

TWST: As you talk to management teams in the sectors you cover, what's their level of confidence now?

Mr. Jonas: I think they are pretty cautious at the moment. They are glad to see clarity in health care reform. And it's somewhat neutral for devices, but they can go ahead and plan for their businesses now. They are very confident in international growth, a little less confident in the overall economy and the impact on procedure volumes. But health care is a defensive industry that is continuing to grow, so I think there is still a fair amount of cautious optimism out there amongst the management teams.

TWST: What are investors' perspectives on the field and the sector at the moment?

Mr. Jonas: I think a lot of investors have been avoiding the sector throughout the health care reform debate. They didn't like the uncertainty. Maybe they didn't understand all the complexities of the bill, with the taxes versus the extra volume that the industry is going to get. So I think it's been out of favor for a while, and health care stocks trade at lower multiples than the S&P overall. So I'm again cautiously optimistic that now that we've got some clarity, that this could start to move back towards a more normal multiple and kind of more normal level of investor interest going forward.

TWST: Given the sense that you have of cautious optimism, what are you advising investors to do at this point?

Mr. Jonas: I think you just have to be very stock specific. Look at who has the best organic growth, who is going to benefit the most from reform, and put your money to work along those principles. Some of the retail pharmacies are going to get a lot of extra volume and benefit from both the generic wave and health care reform over the next few years. They didn't have to pay any taxes or accept lower reimbursement to get that. I think large-cap pharma struck up a very positive deal with the government and that they will benefit over time. While they did agree to significant taxes and discounts, they maintain their pricing power and continue to shift towards biotech drugs with 12 years of exclusivity. With device companies, again, it's a little bit company specific. Reform is probably neutral for them, with the potential for some modest volume gains being offset by the tax. You just have to look at who has the best portfolios, like the names we've covered so far, **St. Jude** or **Genoptix**.

1-Year Daily Chart of Genoptix

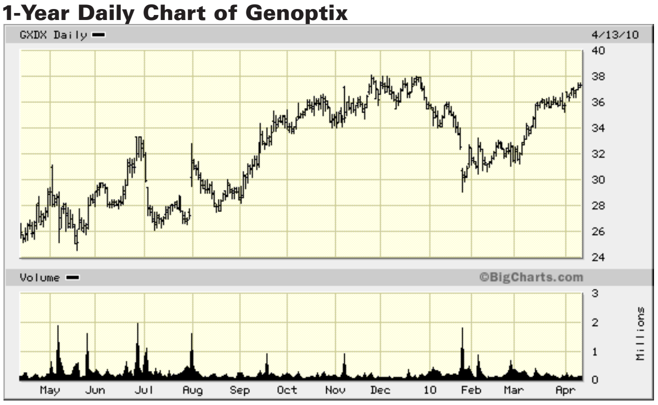

Chart provided by www.BigCharts.com

TWST: As you have discussions about the industry or the medical device sector, is there anything in the debate that's been misinterpreted or misunderstood?

Mr. Jonas: I think that one company that's being misinterpreted is **Kinetic Concepts** (KCI). They make a wound care system that's called vacuum-assisted closure, VAC for short. They've been embroiled in some patent infringement suits for a long time. They are the dominant player in the market and several other companies are trying to enter or to compete with them — **Smith & Nephew** (SNN) is the biggest one and several private startups as well. These companies have already entered the market, and **KCI** is suing them for patent infringement. They recently won a big case in San Antonio against **Smith & Nephew** that found some of the newer foam-based products did in fact infringe, and that's important for them. That gets all the attention, but it's missing the point. It's already a competitive market that **KCI** continues to grow and dominate, so there is only upside from the case. But **KCI** is diversifying away from the traditional wound care market. Most of their growth now is coming from the LifeCell tissue implant business for things like hernia repair and breast reconstruction after cancer. Their new wound care systems are getting into the surgical suite, helping improve both the healing and the cosmetic results that come after surgery. They are diversifying into new markets, like Japan, that don't have the competitive impact. And the recent patent infringement case is only upside. These recent positives are being overlooked by the market; everyone just focuses on the fact that historically competition has been increasing. There was a lot of fear that the business would fall off the cliff, which is why the stock only trades at 11 times earnings, but that's simply not going to happen. They continue to grow and diversify to hold off any of these new competitors.

TWST: Thank you.

Note: Opinions and recommendations are as of 04/05/10.

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Disclosure: Gabelli & Company, Inc., owns shares of BSX, STJ, EW, GXDX, KCI and SNN.

A N A L Y S T I N T E R V I E W

Smaller Medical Device Players Capture Market Share

MATT MIKSIC PIPER JAFFRAY & CO.

MATT MIKSIC is a Managing Director and Senior Research Analyst at Piper Jaffray & Co., where he covers medical technology and hospital supply stocks, with an emphasis on orthopedics, spine and ophthalmology. Mr. Miksic joined Piper Jaffray after spending eight years in equity research at Morgan Stanley, where he was a member of the medical technology and hospital supply coverage team, with lead coverage of orthopedics, spine and hospital supplies. Prior to Morgan Stanley, Mr. Miksic was a Senior Manager with Arthur Andersen in its business consulting division; he also spent five years with a software startup. Mr. Miksic holds a bachelor s degree in computer science from Rutgers College and an MBA from the Leonard N. Stern School of Business at New York University.

SECTOR — MEDICAL DEVICES

(ABF802) TWST: How would you say the industry has changed since we last spoke in September?

Mr. Miksic: I would say that I don't think the industry has changed an awful lot. There have been some evolutionary changes, but even with respect to reform, I don't believe investors are looking at the health care reform bill and enumerating all the different ways it is going to immediately change the med tech or hospital supply industry. I think in the out-years, if we think about increased coverage, it should be a benefit to a varying degree by market and by demographic. But in the near term, certainly in the next two or three years, we don't expect the industry to be changed by this event, even though it's obviously gotten a lot of media attention.

TWST: What are your top stock picks at the moment?

Mr. Miksic: In the large-cap space, we like **Baxter** (BAX). We liked it last year also, but the thesis for 2010 is slightly different than it was for 2009. The story last year was the market was worried. Investors were concerned over stability of the plasma market and the possibility that oversupply would trigger an imbalance in the market, causing the market to deteriorate. Our thesis was that that's not going to happen, based on a detailed analysis of the capacity across the market to produce products like IVIG, albumin and Factor VIII. So by the end of the year, two things happened. One was that the market got comfortable with the idea that there will be ebbs and flows in the supply and inventory of IVIG, but that overall the plasma market will remain stable. That's one thing, which was a meaningful change in the psychology associated with the stock. The second thing that has happened is that the market is beginning to realize that there has been a disproportionate focus on IVIG, out of proportion to the actual economic sensitivity of the stock to IVIG. So we saw a U.S. IVIG business that was growing double digits in the front half of last year, slow to mid-single-digit growth by the back half of the year. But that realization in and of itself did not take much out of the stock, certainly much less than I thought it would have taken out of the stock a year ago. Now as we look into 2010, part of the story is that we are dealing with a slower-growing U.S. IVIG business, particularly in the first half.

> **Highlights**
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> *Matt Miksic discusses his current stock picks in both the large- and small-cap medical devices and hospital supply spaces. He identifies a recent trend of smaller extremities, sports medicine and spine companies taking market share from larger players. Mr. Miksic outlines the strategies those companies have employed to achieve double-digit growth rates. The analyst returns to Baxter International frequently, dissecting the company's divisions and explaining why it's a solid pick.*
> *Companies include: Baxter International (BAX); Zimmer Holdings (ZMH); Kinetic Concepts (KCI); NuVasive (NUVA); Johnson & Johnson (JNJ); Medtronic (MDT); Wright Medical Group (WMGI); Integra LifeSciences Holdings (IART); Synthes (SYST.VX); Stryker (SYK) and Alphatec Holdings (ATEC).*

To put this into context, with all due respect to **Baxter**'s Medication Delivery and Renal divisions, they were significantly

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underperforming Bioscience over the past five years. So the stock has really been a Bioscience story, dragging these other divisions behind it. Going forward, Bioscience remains in itself a very well-diversified portfolio of products, growing in the mid- to upper-single-digit range. But these other businesses have now picked up the pace a bit. There is a new pump product that's driving high-margin pump-set revenues. There are some new nutritional products and anesthesia is still a very good business for the company. So the Med Delivery division is picking up the pace and driving some higher-margin products. Renal is also improving, driven by peritoneal dialysis, which has been historically underrepresented in the U.S. Even in this early stage in the year, we are starting to see a pickup in PD, which changes the profile of the overall stock to one that's driven by three divisions, not just by one.

If you are looking for another stock where we have a lot of conviction, we would highlight NuVasive (NUVA), which has been a favorite of ours for several years. It's what I would call a core med tech growth holding.

1-Year Daily Chart of NuVasive

Chart provided by www.BigCharts.com

TWST: What is the supply and demand balance for the medical devices sector?

Mr. Miksic: I don't think inventories are a big issue anywhere. There was a situation, for example, that — not new news — but about a year ago **Zimmer** (ZMH) was faced with some share losses; they ratcheted down their production. They talked about this throughout last year, that they were working down inventories and operating at lower production levels. That is starting to work its way through their model now. That was one example, but not much evidence that inventories are a widespread problem. These companies, I think, are pretty good at matching their production to demand. The challenge around plasma and the reason why there was such a fear of oversupply and demand imbalance was because there were manufacturers converging on the U.S. market and adding capacity. It's a long-cycle production process — a year or so in terms of collections, regulatory procedures regarding testing and safety, and finishing these proteins into products. So historically it's been difficult for companies to effectively correct their course of production if they were all rushing in the same direction. But our analysis again indicates that they are not.

TWST: Do you have a "sell" rating on any stocks? In your opinion, which names are underperforming?

Mr. Miksic: We currently have an "underweight" on **KCI**, which is more of a relative performance rating versus our overall universe, but nothing that I would consider a "sell" rating.

We have a couple of small-cap names that we like very much. If you are looking for another stock where we have a lot of conviction, we would highlight **NuVasive** (NUVA), which has been a favorite of ours for several years. It's what I would call a core med tech growth holding. The stock came under a great amount of pressure over the past three or four months due to concerns over reimbursement, but that's since been alleviated and the numbers have just been coming in very solid. We like spine a lot. Here is an example in response to your earlier question of something that has changed a bit in the last several months. One of the dynamics that has been playing out in my universe in certain markets — not all markets, not hips and knees, for example, but markets like extremities, sports medicine and spine — smaller companies have had some success taking share from larger players by leveraging a few common strategies: one, getting high-quality, new products to market faster; two, high levels of service and responsiveness to surgeon feedback. Of course, the products must be innovative, differentiated and competitive with the products of larger players, like **J&J** (JNJ) and **Medtronic** (MDT), which happen to be the market leaders in the spine market. But in a nutshell, that's what drives **NuVasive**'s share gains and has been for the past several years. It's also what's been driving share gains in the extremities orthopedics market, where smaller players like **Wright Medical** (WMGI), **Integra** (IART) and privately held **Tornier** are executing quite well on a similar strategy as well.

In spine, there are four market leaders: **Medtronic**, **DePuy Spine**, part of **J&J**, **Synthes** (SYST.VX) and **Stryker** (SYK), and they all talked about weakness in their respective businesses in the fourth quarter. The conventional wisdom is that if you look at the growth rate of the top five players of any market, covering, say, 70% to 80% of the market, normally you would be able to comfortably assume that you've got a pretty good read on the market. In this case, however, every one of those large players is now losing share. Recently **Stryker**, joining that group, is now losing share to the likes of **NuVasive** and privately held **Globus Medical**, both of which are growing over 30%. **Alphatec**, also a smaller player, is now growing at almost 30% annually. **Biomet** was public, went private and turned its spine business around, which is now growing over 20%. **Integra Spine**, a small player, is also growing north of 20% by our estimates. So all these small players are executing on the strategy that I described with varying degrees of success, and they are all taking share from the large players. So the conventional wisdom is that spine must be really slowing down because the growth rates of these four largest players is slowing. We would say that it's just the opposite. And for these smaller players, like **NuVa-**

sive, to all be growing in the 20%s and 30%s, the market must be hanging in there. In fact, if you add up all the numbers, we estimate the spine market is growing in the 10% to 11% range.

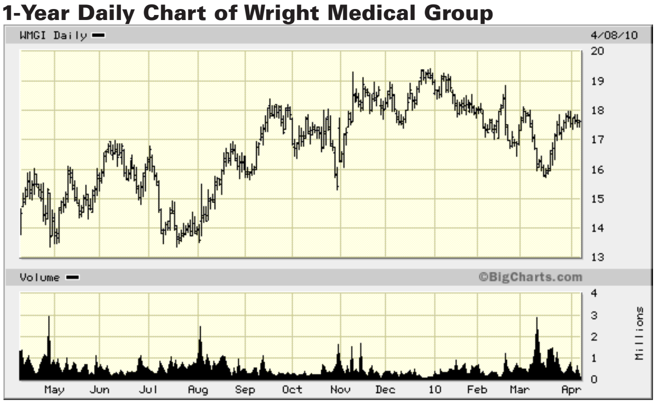
TWST: What are managements' opinions and the level of confidence at the moment?

Mr. Miksic: We have not seen broad-based hiring, but we are seeing investments in areas where companies can take share and grow their business. A good example is **Wright Medical**, which announced as part of their 2010 guidance that they will be investing in their extremities business, where they can get a great return on their investment in the form of growth and share gains. So they are adding sales reps there; they may indeed add some new products there. But when you have a business that's growing 15% to 20% and taking share, generating operating margins of approximately 20%, I don't think you want to be squeezing cost out of that business. You want to be investing in that business. So there are areas where companies were doing that.

[W]hat we see now that the bill is signed in, stocks are actually behaving well again. We may not like the final bill, we may not agree with the excess tax, we may not believe that it's going to solve all the problems in the health care system, but the completion of the bill reduces uncertainty.

On the other end of the spectrum, we see hospitals, which have clamped down on capital spending and budgetary decisions at all levels over the past 12 months to 18 months, and there is no sign that they are unwinding those controls. They are certainly reviewing every purchase carefully as they have over the past 12 months. They are selectively buying but generally in areas where they can get a return or where they must spend to repair and maintain operations.

1-Year Daily Chart of Wright Medical Group



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TWST: Where is current investor interest in this space, given the recent health care reform and state of the economy?

Mr. Miksic: I think on the first point, the health care reform in some ways kind of whipsawed investors earlier this year. The reform issue came onto the scene about a year ago. It put a lot of pressure on health care stocks, but as we got closer and closer to a certain resolution of some kind, whether we liked it or not — regardless of whether we felt it was a good idea or a bad idea politically, or from budgetary standpoint or competitively for this country — the closer we got to resolution, the better stocks were behaving. As we headed towards what we thought was going to be a final result on health care reform in January or February, that would remove the remaining uncertainty as to how much of a tax that we're going to pay and what the impact was going to be, then we, as you know, took a few steps backwards after the Massachusetts election. And even though intuitively you might expect this would be great for health care stocks because this meant that health care reform wasn't going to happen anymore, but what it really meant was we don't know what's going to happen next. So I think that uncertainty washed a lot of the enthusiasm out of the health care sector, and it sort of threw that recovery, that health care reform resolution trade, kind of off the rails.

What we're seeing now, what we see now that the bill is signed in, stocks are actually behaving well again. We may not like the final bill, we may not agree with the excess tax, we may not believe that it's going to solve all the problems in the health care system, but the completion of the bill reduces uncertainty. So I think enthusiasm for these stocks is going up, and I think it will go up further and attract generalists who have been avoiding this sector.

On the economy, I guess going back to the way I answered the question at the top is I don't think there's been any meaningful change in the slope of recovery or data points that would tell us that it's going faster or slower. I think many of the markets that we cover are in kind of a steady risk-recovery phase, and there is a handful of markets that you could argue are a little bit more unemployment correlated maybe and consumer correlated, which may push their recovery cycle a bit further out through the end of this year or sometime next year. And I don't think that's changed.

TWST: You mentioned how the stocks might benefit. Do you think any particular subsectors are more likely to benefit than others and why?

Mr. Miksic: Benefit from the health care reform?

TWST: Yes.

Mr. Miksic: I think that you could make the argument that it's a younger patients' bill because older patients for the most part will have at least Medicare and oftentimes something maybe better than Medicare in the current environment. So when you're talking about adding new covered patients, I think you have to think about the incremental benefit being towards the younger patient population. So that would mean spine, for example, that's a patient population that's only about 20% Medicare, 80% private pay and therefore an area that could benefit from additional coverage. Trauma and extremities could also benefit as well as sports medicine, all of which have exposure to younger patients. Those are some of the areas in my space that could benefit from added coverage.

TWST: What are you advising investors to do now?

Mr. Miksic: We've been buyers of health care ahead of what we expected to be a resolution of health care reform earlier in the quarter. So we are certainly buyers of health care generally today. We don't often look at what's going to move the most in the next month that makes a call, but I would highlight the fact that many of the names in our group with narrower profit margins were singled out about six months ago, when the excise tax emerged in its prior form, which would have taken a greater toll on these companies as a percentage of profit. So names like **Wright Medical** and **NuVasive** got clipped much harder back in September and October, and as a result within my space, I would argue that they will see a bigger bounce-off of the resolution of the reform bill.

TWST: Do you find any concepts to be generally misunderstood in this space or missed entirely by other analysts?

Mr. Miksic: A couple of things. One of them I think I mentioned was the idea that the market perception is that the spine market is slowing significantly. As I mentioned, our analysis indicates that when all the smaller players are included in the market, which is the way we look at it, growth is actually hanging in there pretty well. In many ways, we view spinal fusion as a surgery of last resort, similar to trauma. Candidates for fusion have tried physical therapy, often other interim operations and injections, pain medication and are in pain that prevents them from working, sitting or lying down comfortably, exercising and so on. So that's one, I guess, the difference we would have with, I would call, conventional wisdom of the Street.

The second point I would say where we differ from the Street is with respect to **Baxter**. The investor psychology around **Baxter** has really been hyperfocused on IVIG, and I think if you would ask someone a year or two ago how big is IVIG or how high are the margins of IVIG, the thinking would have been it's a very high-margin product; it's the biggest product in the Bioscience division, and it's driving most of the margin. And therefore the fear was that when it stops or slows down, it's going to kill the fundamental story of the stock. What we have been emphasizing over the past six months is if you dissect the Bioscience business, **Baxter**'s U.S. IVIG business is around $1 billion. Recombinants, also part of the Bioscience division, is twice the size of the U.S. IVIG business, with twice the profit margins. So it's an important product and an important part of Bioscience. But even though it's counterintuitive, as IVIG slows against a steady Recombinant growth rate, mix actually improves, which is not what most investors would have expected until they drilled into the numbers. So we've been emphasizing products like pump sets, which don't sound very sexy or exciting, but they carry a higher margin than IVIG. Nutrition also doesn't sound very exciting, but it's higher margin than IVIG as well. Anesthesia carries quite high margins. And many of these businesses are turning around and continuing to grow faster than the IVIG business. Conventional wisdom has been that **Baxter**'s growth and margin story is sort of over now because IVIG is slowing in the U.S. I think that's sort of backwards, so we'll be driving that thesis home this year.

TWST: Thank you. (MRR)

Note: Opinions and recommendations are as of 03/23/10.

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COMPANY INTERVIEW

Dynatronics Corp. (DYNT)

KELVYN H. CULLIMORE JR. has been Chairman of Dynatronics Corp. since January 2005, and President and CEO since 1992. He served as Secretary/Treasurer from 1983 to 1992 and as Administrative Vice President from 1988 to 1992. Mr. Cullimore graduated cum laude from Brigham Young University with a bachelor's degree in financial and estate planning. In addition to his involvement with Dynatronics, Mr. Cullimore served as Executive Vice President and a Director of its former parent company. He currently serves on the board of directors of ITEC Attractions, Inc., an entertainment, restaurant and retail mall operation in Branson, Mo. Mr. Cullimore also serves as the Mayor of Cottonwood Heights, Utah, a suburb of Salt Lake City, where Dynatronics' corporate headquarters are located.

SECTOR — MEDICAL DEVICES

(ANT603) TWST: Would you begin with a brief historical sketch of the company and a picture of the things you're doing at the present time?

Mr. Cullimore: Dynatronics is a manufacturer and distributor of medical devices and supplies. This is the physical medicine market. Specifically, that's physical therapy, chiropractic and athletic training. Dynatronics has been in business for about 30 years and on Nasdaq since 1984. We have in the last couple of years done some vertical integration that took us from being solely a manufacturer with some distributed goods, to having a direct sales force. And we've also started distributing products to other companies. So we've gone through some real big transitions in the last few years.

TWST: Tell me a little bit about your own background and those of some key members of your team.

Mr. Cullimore: I'm one of the founders of the company. My father and I started the company back in 1979, so we've been involved from the very beginning. The company started off trying to get approval for a laser device that was not successful, but we pushed it through the process. And by the early 2000s, the FDA had approved that particular device. So it's kind of a unique start for the company. Most of the people that are in top management of the company have been with us 15 years or longer, with one exception. So we have a very seasoned management team, one that understands our industry extremely well.

TWST: How would you describe the outlook for the industry in general and for your company in particular right now?

Mr. Cullimore: Dynatronics is in a segment of the industry that should benefit greatly from the increased Baby Boomers or the aging Baby Boomers. The need for physical therapy services and rehabilitation services continues to be a growth industry, not just from the aging population, but also from a more active population. And so we feel that we're in a very good market. The physical therapy market should benefit also from increased health care from the "Obamacare" announcement; the more people that have insurance, the more that will be seeking treatments. So it will be interesting to see over the next few years how that plays out.

TWST: Do you feel pretty positive about health care reform as it stands right now?

Mr. Cullimore: Well, certainly there will be some companies benefiting, some that don't. A lot remains to be seen, how it actually is implemented. We believe there's certainly an opportunity for Dynatronics to benefit from greater sales as a result. All medical device manufacturers are going to have to raise prices because there is a tax being levied on medical device companies. But that means that taxes get passed along to the customers. So that might have a little bit of a dampening effect, but the increased demand for services should more than offset that.

TWST: You had a price increase recently. Was that a positive development for you?

Mr. Cullimore: It was about a year and a half ago we did the first price increase on our capital equipment in the history of the company. That was a necessary change to catch up with some of the increased costs of doing business, and it did not seem to have a dampening effect on the sales.

TWST: What's the competitive landscape like and what do you see as some of your competitive advantages?

Mr. Cullimore: Dynatronics is in a unique position. There are only two companies in our industry that have a direct sales force. The other company is not a manufacturer, they are a distributor only. So we're the only manufacturer and distributor who has its own distribution channel. We think that's a distinct advantage and gives us the opportunity to go right to the market with information and products that we think are very attractive. Dynatronics has strong intellectual property on its devices, which makes them very attractive. We have a great history of service and reliability. So as far as the market itself goes, we have a distinct advantage because we're the manufacturer of the highest-margin items; they have a great reputation. We now have a sales force that is the most educated and knowledgeable sales force on capital equipment in our industry,

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and we're one of the only two companies that actually has a direct sales force on the street. So we believe we're in a pretty unique position to compete.

TWST: How has the recession impacted Dynatronics?

Mr. Cullimore: Everybody has been impacted by the recession. Sales are more difficult, people are more cautious, especially on the capital-equipment side. Just prior to all of this occurring, we concluded the acquisitions I had mentioned earlier and had just concluded a very, very difficult year, where we had lost several million dollars. And now that that's turned around, we've generated six consecutive quarters of profitability, maintained or increased sales despite the recession. And so given the background of that recession, we're quite pleased with the turnarounds that have occurred. A year and a half or two years ago, there were people writing us off, thinking that we weren't going to survive. And not only have we survived, we've thrived.

"We've established preferred vendor agreements, with national and regional accounts representing over 2,500 clinics. Our most recent agreement was with WorkWell Systems, and they alone look like they'll add another 2,000 clinics. So we're in a position where national accounts are more attracted to us and as their current contracts expire, we become a very viable option."

TWST: What do you mean by capital equipment?

Mr. Cullimore: Durable equipment that we manufacture as opposed to consumable supplies. Consumable supplies are always in demand. As long as you are treating patients, you've got to have them. Capital equipment is more durable. You may put off buying that new treatment table, and you may put off buying those new electrical stim units or something of that nature. And so we have recognized that the supply side of the business is pretty constant. Capital equipment sales dipped during the recession, but because we have the supply side of the business as well, that increased. And now capital equipment sales for the last six months have begun to show a significant improvement.

TWST: So you're seeing a positive trend in spending among physical therapists, chiropractors and trainers?

Mr. Cullimore: Yes, there have been some changes in our market that have given us an opportunity to acquire some large customers. We've established preferred vendor agreements, with national and regional accounts representing over 2,500 clinics. Our most recent agreement was with WorkWell Systems, and they alone look like they'll add another 2,000 clinics. So we're in a position where national accounts are more attracted to us and as their current contracts expire, we become a very viable option.

TWST: In February you reported net income up 245%, and that was right after you announced that you had regained compliance with Nasdaq minimum share price requirements. First off, would you give me a sense of what problems you had prior to this period?

Mr. Cullimore: Well, there is no question, it was the acquisitions in 2007. The fiscal year ending in 2008 was a very difficult year for us. We lost about $2.5 million plus had to write of about $6.5 million in goodwill. It was a very devastating year from that perspective, and that was announced in the fall of 2008, which is right when the recession began. So combining all those things together, our stocks started to tumble, and I think by March of 2009, it dropped down to as low as $0.17. So over the last year, Nasdaq has granted postponements of implementing the dollar minimum bid and then didn't do that any longer. Fortunately, we've turned things around and the company was showing significant profits again, and the market responded. With the announcement of that one quarterly increase that you just mentioned, with over 200% increase over the prior year, the market responded very positively and pushed us back up over a dollar.

TWST: Would you tell me how you addressed those issues and how you were able to post increased profitability?

Mr. Cullimore: Yes, the big challenge was rationalizing — after buying six other companies, all within two days — rationalizing all the costs. And it just took a little bit of time, a little longer than we expected, to get all those costs rationalized. But we were able to maintain sales while cutting costs dramatically and increasing profitability. While sales have not increased dramatically — I think they are up a couple of points over the prior year — the big change came, improving margins by a couple of points and cutting our costs significantly. For instance, one of the things we've been doing is we've launched an e-commerce solution. That alone will lower our costs, when we launch that next month, quite a bit. And so again, one more tool in the workbox to make sure that we remain profitable and increase that profitability.

TWST: What's the strategy going forward over the next four to eight quarters?

Mr. Cullimore: We have multiple strategies. Number one, we anticipate introducing some new products, which will always help out. So in the next four to eight quarters, you should see some significant product introductions. We're working on some large national accounts. That's where our focus is because we're now a broadline distributor as well as a manufacturer. So it won't be bringing on one clinic at a time, but big chunks of clinics to do business with us. We're introducing our e-commerce solution, which will make it much easier to do business with us and allow us to reach out into broader markets. We'll continue to focus on the strength of our distribution network and we'll be looking at international expansion, which has been a difficult arena for us in the past. We believe it can be a very positive thing in the future. So we have a big focus on new products, focusing on big accounts. We have a focus on capitalizing on our distribution network and introducing the new tools, making it easier to do business with us.

TWST: What pushed you into this space, in which you're going after these big accounts?

Mr. Cullimore: It was the acquisition. It was a vertical integration that we did two years ago. Instead of just being a manufacturer of a smaller segment of the product line, we now offer over 12,000 products instead of a couple of thousand products. That broadline offering now makes us an attractive alternative to large accounts who like to try and find a single source to deal with. And so by offering the competitive value of local service through our distribution network, the best products — which we've always been the manufacturer of — plus the added benefit of doing business with us on distributed items, makes us truly an attractive option for these large national and regional accounts.

TWST: When you spoke with us last fall, you mentioned the V-Force vibratory therapy device, which was then newly released. You also hinted at some other new products. How has the V-Force turned out for you and do you have any other products you are particularly excited about?

Mr. Cullimore: Yes, the V-Force was an exciting product to introduce. Unfortunately, it came at a time when demand for any kind of capital equipment was diminished and a high-ticket item like that was even more difficult. So we have not realized the same bump in sales that we had hoped for, but it has been well received in any practice that focuses on geriatrics or athletic training. Those are the two arenas where it has done well, and we anticipate it will continue to do well. New products coming out in the future, I wish I could talk about, but I don't want to give away the secrets. We do have some exciting new products that we will be introducing in the next four to eight quarters.

TWST: Has the company given lot of attention to investor relations? Do you feel investors have a clear understanding of what you offer?

Mr. Cullimore: We do our best. I think the challenge for any micro-cap company like us, or nano-cap company, is that we are not eligible for a lot of fund investments. And so we rely heavily on individual investors, and stock newsletters and things of that nature. I believe that we've been around long enough that we're fairly well-known to many of those people, and it does seem to make a difference when we give them good news. It does seem to help.

TWST: Looking ahead, what might be some year-by-year milestones or indicators that investors might look for?

Mr. Cullimore: Our fiscal year ends on June 30 of 2010. I think fiscal year 2011 is going to see a continued increase on the bottom line and on the top line. We've not done a lot on the top line in the last year. It's been increased slightly, but I think with all of these national accounts we are bringing on, there is a real potential for top-line increase. And with tools such as our e-commerce in place, we should be able accommodate that additional business without a significant increase in overhead or support costs, which should result in better earnings on the bottom line. So I would expect that over the next year, we should see year-over-year improvements both on the top and bottom line.

TWST: What would be the two or three best reasons for a long-term investor to look closely at Dynatronics?

Mr. Cullimore: I think number one, it's a matter of looking at what has happened within our current marketplace. There have been a lot of changes within our specific market that have positioned Dynatronics uniquely for growth. One main competitor was bought out by another one, and a main manufacturing competitor was recently closed down, with its operations redistributed to other operations within its parent company. Those unique factors have put Dynatronics in a position to take advantage of that and see some significant growth in the next year. That's one factor, so just our general market.

Number two, if you look at the history of our stock and you look at the price, we've been in business for 30 years. We're a solid company, strong balance sheet, things are looking good. And if you look at our history, it's not unusual for us to trade in the $2 to $3 range. And I think as we achieve some of our milestones, we should be back into that kind of range for someone who is looking for a long-term hold. And we've done it before. So it's not something that we're hoping for, it's something we've done.

Finally, it's just the fact we've been able to do well in a recessionary period. So if we can do well in a recessionary period like this, it certainly means that if the economy starts to turn around even just a little and demand for capital equipment improves, there should be some pent-up demand that will help boost sales and profits as well. Let me add to that the potential impact from more universal health care availability, and I think there are a lot of reasons to look positively at Dynatronics.

TWST: Anything else you want to touch on or anything else that investors should know?

Mr. Cullimore: I think if they look, they'll see there are large blocks of stocks that are held by inside shareholders, and those shareholders are very committed. And so I think that's also a good sign.

TWST: Thank you. (MJW)

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COMPANY INTERVIEW

EDAP TMS S.A. (EDAP)

MARC OCZACHOWSKI joined EDAP TMS S.A. in May 1997 as Area Sales Manager, based in Lyon, France. From March 2001 to January 2004, he was General Manager of EDAP Technomed Malaysia. Mr. Oczachowski was appointed Chief Operating Officer of EDAP TMS in November 2004 and became Chief Executive Officer of the company in March 2007. Previously, he was Area Sales Manager for Sodem Systems, which manufactures orthopedic power tools. Mr. Oczachowski is a graduate of the Institut Commercial de Lyon, France.

SECTOR — MEDICAL DEVICES

(ANT602) TWST: Would you begin with a brief historical sketch of the company and a picture of what you are doing at the present time?

Mr. Oczachowski: The company is now 30 years old, and we have always been focused on developing, manufacturing, distributing and servicing a range of products specializing in therapeutic ultrasound, mainly in the field of urology. We basically address two major pathologies in urology. One is our lithotripsy division, addressing kidney stones and urinary tract stones, and the other is our HIFU division, for high-intensity focused ultrasound, which addresses localized prostate cancer. The company is recognized for our extensive expertise and worldwide leadership in therapeutic ultrasound.

TWST: Tell me a little bit about your own background and those of some key members of your team.

Mr. Oczachowski: I went to the University of Biology in Lyon, France, and then International Business School, also in Lyon, France. After school, I worked in the pharmaceutical industry for two years and then in the orthopedic device industry for another two years. Following this, I joined EDAP TMS 13 years ago as a Sales Manager for Latin America and the Middle East. I was based in Malaysia, in charge of the Pacific area, and then came back to Lyon in 2004, first to manage EDAP's lithotripsy division and then the whole group. I was promoted to CEO of the company three years ago.

TWST: You're headquartered in Lyon?

Mr. Oczachowski: Yes, the headquarters of the company is in Lyon, France.

TWST: How would you describe the outlook for the industry in general right now and for your company in particular?

Mr. Oczachowski: For medical device companies and the overall market, it has of course been challenging over the past two or three years, given the economic downturn, though that is mainly in the U.S. and predominantly for larger capital equipment companies. So our company, being positioned as a mid-sized capital equipment provider with minimal sales in the U.S. at this point — we are conducting a PMA clinical trial for Ablatherm-HIFU and recently received U.S. approval for our Sonolith I-Sys lithotripsy device — has not been significantly affected by the economic crisis over the past three years. This is one of the reasons we announced during our 2009 results call that we have achieved record revenue for the past three consecutive years.

TWST: How does your business break down by country or region?

Mr. Oczachowski: Most of the business in terms of revenue is generated from Asia and Europe, and we recently received U.S. approval for our Sonolith I-Sys lithotripsy device in August 2009. We sold our first device in the U.S. in Q4 last year, and we have since commercially positioned the company to fully enter the U.S. lithotripsy market in 2010. So our U.S. sales operations, I would say, are beginning to ramp up. South America and Latin America are also generating revenue for the company as well, but most of the business is in Europe and Asia. And if you look at the revenue stream from both of our sales divisions, 60% of our revenue is from lithotripsy, which is the historical business of the company, and 40% comes from HIFU for the treatment of localized prostate cancer. HIFU is a new and innovative technology that the company is bringing to market that will leverage and drive our growth.

TWST: Where are you targeting growth geographically? Are you preparing for more business in the U.S.?

Mr. Oczachowski: As far as lithotripsy is concerned, we received approval of our latest model, the Sonolith I-Sys, in Japan a few weeks ago. The exciting thing is that Japan is the biggest market for lithotripsy in terms of the number of machines installed. We are expecting this to continue to drive our lithotripsy growth in Asia and particularly in Japan. And we are also expecting to add some additional revenue in the U.S., promoting the Sonolith I-Sys. We are expecting to recognize additional revenues from these new territories where we have our latest machine approved, and we are continuing obviously to promote this machine in Europe and the rest of the world.

TWST: The recent approval of the Sonolith I-Sys device in Japan certainly had a positive effect on your share prices. What does that mean for the company?

Mr. Oczachowski: Again, the Japanese market is the largest market in the world for this type of equipment and the company is very well positioned, as we have had our own subsidiaries, and sales and service teams in Japan for the past 15 years. We are

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extremely well positioned in this market. The Sonolith I-Sys machine is a very high-end, robotized and motorized device that meets the Japanese demand for very high technology and the latest innovations in the medical field. We were already promoting our earlier generation litho device, which is a lower-range product that has been very successful in Japan. We are expecting the new Sonolith I-Sys machine to contribute even greater sales growth in the region. We are excited about its potential.

TWST: You also have some devices in trial in the U.S. right now, correct?

Mr. Oczachowski: That is for the HIFU division. As I said, the Sonolith I-Sys has been approved. We started to sell units during the end of 2009, and we are actively promoting the machine so that we can generate additional revenue in 2010. Now on the HIFU side, where the U.S. represents the biggest market for prostate cancer in the world, we currently have a clinical trial underway. We currently have three machines based in the U.S. that are mobilized between 15 clinical sites, which are among some of the most prestigious hospitals, such as Sloan-Kettering in New York and M.D. Anderson in Houston.

"Most of the business in terms of revenue is generated from Asia and Europe, and we recently received U.S. approval for our Sonolith I-Sys lithotripsy device in August 2009."

TWST: Any sense of how long that process takes?

Mr. Oczachowski: That is a good question, and it is a difficult one to answer. We are currently in discussions with the FDA and have held several meetings with them and with a panel of experts approved by the agency to answer questions regarding the study's protocol. Therefore, today we cannot really say exactly what the time frame will be, but we are committed to delivering clinical results as quickly as we can. We are planning to announce a clear plan and strategy for our U.S. clinical trial by the end of April.

TWST: What's the competitive landscape like and what do you as your competitive advantages?

Mr. Oczachowski: For the lithotripsy market, it is a very mature and competitive market. There are a lot of players, and I would say that one of the main competitive advantages for EDAP is our superior patented technology. It is exclusive and that means our machines have the best and highest efficiency quotient, as reported in the scientific and clinical literature. With regards to HIFU, which again is a new technology in a very new but fast and growing market, particularly in the U.S., we only have one competitor. There are some differences technologically and there are also some differences in terms of the development of the device. EDAP's Ablatherm-HIFU was the first HIFU device to be used on a routine basis worldwide for the treatment of prostate cancer. And that is a big advantage as well because one of the key points for evaluating a technology that treats prostate cancer is based on long-term results. Based on that and based on some technological differences, we currently have about 90% of the market in Europe, where the technology is currently approved.

TWST: How was the company impacted by the recession and the current economic environment?

Mr. Oczachowski: Again, I believe the recession was quite strong, particularly in the U.S., but did not have as significant an impact in Europe. We have not significantly felt its effect thus far, but it may take time. Usually the medical field and the health care industry are insulated a bit by recessionary effects. When the health care system is affected, it is cause for concern. But I am pleased to say that we have continued to grow our revenue for the past three consecutive years. Still, I would say that the recession is not yet over, and sometimes its effects lead to a more difficult process. I mean, purchasing processes are longer, projects are a bit slower, and I would say there are fewer hospitals investing. I would not go as far to say that hospital purchasing patterns over the last two to three years have matched the global recession.

TWST: Do you see economic challenges still ahead in European markets?

Mr. Oczachowski: Yes, I think so. I think we hear a bit less about it but in terms of doing business, we do not see a lot of differences between last year versus two years ago. However, it is still challenging. Again, purchasing decisions are harder, budgets are much more limited than what they were three or four years ago. There is still business, but it is a bit more challenging and it takes a bit more time.

TWST: Do you have a sense of what U.S. health care reform will mean to the company as you come to market?

Mr. Oczachowski: I think there will be some time before we feel its effects. As it relates to our business, there have been some discussions, particularly in the field of lithotripsy, during 2009 on legislation known as the Stark Law. At the end of 2009, it was said that lithotripsy was still exempted from that clause and nothing was changed, so we have not seen any change so far. Again, we are still conducting trials for HIFU in the U.S., which again represents significant growth potential for the company. Since we are still in the FDA approval process, which may take another few years, we will not be greatly affected in the near term by the new reform.

TWST: Yesterday you reported record revenues, an increase in gross margin and a cash position of $18.2 million. What were the keys to such a positive 2009?

Mr. Oczachowski: Again, we have been working very actively in expanding our technology in existing markets that we are currently approved in. But we have also penetrated new markets, with Ablatherm-HIFU and our Sonolith I-Sys lithotripsy device. This has helped to significantly grow our revenue. On a gross margin basis, we have worked to decrease costs and increase the efficiency of our processes. Our fourth quarter and full year 2009 gross margin expansion also reflected higher sales volume. Concerning our cash position, we are extremely cautious about capital. During the current economic environment, we are trying to be even more cautious concerning investments and expenses. If we make any investment or incur any expense, we expect a very quick return.

TWST: What's your philosophy on M&A, joint part-

nerships or other tools that you might use to grow?

Mr. Oczachowski: We are not currently on this path, but again we are a public company, so a lot of things can happen and opportunities can arise. We would evaluate these types of projects if the potential was there to bring more speed and strength in growing our businesses and establishing our technologies in new worldwide markets.

TWST: We talked about your FDA trials. What else is on the docket as far as getting approval from regulatory agencies?

Mr. Oczachowski: Not in major markets. We received approval for our technology in several new markets last year. One of our main initiatives is to work on U.S. FDA trial.

TWST: Does the company give a great deal of attention to investor relations? Do you feel you've gotten the word out as to what you have to offer to investors?

Mr. Oczachowski: We are working on that, and we work with a good group who provide IR support. We typically go on U.S. road shows to meet with investors every few months, and we try to participate in investor conferences as well. We try to be as clear as we can and reach as many investors as possible.

TWST: How do you continue to increase your presence in the U.S.?

Mr. Oczachowski: We work constantly on establishing new strategies and ways to increase exposure, and we have been improving on this initiative over the past few years. I mean, look at the increase in our daily trading volume. We believe that we are improving on this and will continue to increase company visibility among U.S. investors.

TWST: Looking ahead, what might be some year-by-year milestones or indicators that investors who are following EDAP should look for?

Mr. Oczachowski: We look for our revenue to very closely follow HIFU growth, particularly in our core business model, which is what we call RPP, or revenue per procedure. That is the number of treatments we sell to hospitals and perform with our HIFU technology. This is a strong indicator of the progress we have made in establishing HIFU as a proven and effective technology in the treatment of localized prostate cancer. This is one of the primary growth drivers for the company. We also expect growth in our lithotripsy division, but this is a mature market so we are not expecting as much growth as with our HIFU division. Our growth will predominantly come from HIFU. Being a new and innovative way of treating prostate cancer, it is a technology that meets the needs and new demands for treating prostate cancer. It is noninvasive, safe, proven and offers patients a very high preservation of quality of life. That is going to be real the growth driver for the company, and this will basically be the main indicator for the company's performance.

TWST: What would be the best reasons for a long-term investor to look closely at EDAP?

Mr. Oczachowski: I think it is the overall growth of the prostate cancer market and the potential of HIFU to become the standard of care in treating localized prostate cancer.

TWST: So it's a relatively new way to treat that disease?

Mr. Oczachowski: Yes, it is a new way. Even though it has been on the market for the past few years, and we have been CE marked and therefore an authorized marketer in Europe for 10 years, 10 years in prostate cancer is a very short period of time. You need to show 10-year data as a minimum so that you can start showing clinical evidence to the urological community and patients. We are approaching that point and therefore see potential for significant growth. I mean, that is the starting point for the development and the standardization of the technology, as we will show long-term results of eight to 10 years in the near future.

TWST: When you get the word out from clinical trials, do you feel this treatment method will become more of a standard for prostate cancer patients?

Mr. Oczachowski: We are about to get that and there have been recent publications from the French Urology Association in 2008, which performed a review of the literature over the past eight years. The organization recognized HIFU technology as a standard of care for prostate cancer. We received the same type of recommendation last year in 2009 from the Italian Urology Association. So things are coming out. Last year, we put in place a registry allowing us to collect all data from all centers since patients were first treated with Ablatherm-HIFU, so that we can work on publishing a very large cohort of long-term data. We plan to publish these results to continue building clinical evidence that will further deepen awareness and acceptance of the treatment among the urological community. We believe we are now at the starting point of being able to show and present these types of results and are confident in the future of EDAP.

TWST: Thank you. (MJW)

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Vycor Medical, Inc. (VYCO.OB)

HEATHER N. VINAS brings extensive experience in the development of international and domestic revenues, having been across the globe in the promotion of numerous highly innovative and specialized medical devices. As the Founder, President and Chairwoman of Vycor Medical, Inc., she is responsible for exploring new and emerging markets, and broadening global sales channels through business development, forging worldwide alliances and expanding the distribution network, all in an effort to streamline the supply chain and improve the bottom line. Prior to Vycor, Ms. Vinas was Director of Sales and Business Development at Misonix, Inc., a Nasdaq-listed medical device company that specialized in ultrasonic surgical devices for orthopedic, neurosurgical, wound, laparoscopic and urological applications. Previously, Ms. Vinas oversaw the capital purchases for new equipment and technologies at Good Samaritan Hospital.

SECTOR — MEDICAL DEVICES

(ANT601) TWST: Would you begin with a brief historical sketch of the company and a picture of what you are doing at the present?

Ms. Vinas: I founded the company back in 2005. And the idea behind the company itself was that there has to be a better way, a more simpler way, to do complicated neurosurgical procedures. Our focus has been on the ViewSite Brain Access System (VBAS), primarily because it's an untapped market. It's an area where essentially the technology has not changed in over 87 years, since the pioneering days of the grandfather, if you will, of neurosurgery, who is Harvey Cushing. Traditionally, what they've been doing and what neurosurgical residents are trained to do is retract back the brain tissue to allow for access to the surgical site. And then their working channel is essentially created by putting cottonoids or multiple blade retractors within the surgical site to allow the surgeon to gain access to the intended target.

I met a neurosurgeon, Dr. John Mangiardi, while I was at Misonix Incorporated, and he had a concept for a much-improved retractor. It was a simple concept that seemed to make perfect sense. After the company's CEO formally turned it down because it was outside of the company's core technology and he wanted to remain focused on products already under development, I decided to pursue this on my own. That was back in 2005. From there, I started the company called Vycor Medical. And Vycor Medical means "at the center of life," which I believe the brain is.

I've always had a very strong relationship to the field of neurosurgery specifically, as it's a personal issue to me. When I was a young girl, my older sister was diagnosed with a pituitary adenoma, which is a tumor on her pituitary gland, and it had a lot of life-changing results for our family and certainly for her. She's been on medication every day since that time when she was 14 years old, when she was first diagnosed. So I've always had a personal connection to the neurosurgical field, and I just find it absolutely fascinating what can be done with neurosurgery today. But when you break that out, how little has been done in the brain aspect of neurosurgery, it is mind-boggling. When this idea came, it's almost like it was a sign from above. Everything happens for a reason, and I believe that that reason was for Vycor Medical to take this product out to the market. And that's exactly what we did.

TWST: So the product you are talking about is the ViewSite Brain Access System?

Ms. Vinas: That's correct. Our first product line is our ViewSite Brain Access System, which is a self-retaining brain access system, comprised of 12 different sizes as of today that allow the surgeon to gain access to various regions of the brain. So whenever there's a craniotomy that's performed and open surgery is needed that is deeper than 2 c.m., we want the VBAS to be used to allow the surgeon a better method of tissue retraction for a complicated procedure. It becomes a vehicle, if you will, for him to get into the brain, monitor the surrounding brain tissue, evenly disperse the brain tissue throughout insertion and provide a defined, working channel. VBAS was designed to keep venous pressure at a minimal rate and also limit the cortical shift that occurs with our device as compared to traditional brain retractors.

TWST: It's out on the market now and has been for a little while, correct?

Ms. Vinas: Yes, we formally commercialized and launched the product through our distribution network back in 2009. So it's just about a year now that the company's products have been on the market. As of December 2009, we had over 800 surgeries that were carried out utilizing the VBAS, with over 50 U.S. hospitals that have approved our product for use and actually purchased the product. We have about another 100 hospitals either going through the approval process or in the evaluation process of the hospital approval committee.

TWST: What type of market do you see for it over time?

Ms. Vinas: We are looking to use our existing devices as

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stand-alone devices, and we are also looking to add additional models as part of the VBAS system and finally integrate the devices with image-guided surgery companies. Essentially, they are the software experts. So what they can do is upload our dimensions and have their software recognize our devices so that the surgeon will have not only a working channel, but also allow him the accurate trajectory for his target and to know exactly where he is at any given point during the procedure. So with that, we believe that it's about a $200 million market potential worldwide, and we are shooting to address about 70% of the addressable procedures. We're also looking to become the standard of care for brain retraction because right now standard of care is those malleable blade retractors. And it's funny because in leaps and bounds, neurosurgical development and breakthroughs are significant, and yet brain retractors have not made those major inroads. That just goes back to my whole ideology that sometimes it's the simpler things that are overlooked. As Albert Einstein once said, "Everything should be made as simple as possible, but not simpler." We're completely well versed in understanding that. This is not a complicated technology, I'll be the first person to tell you that. We've been in the ORs and have seen a lot of the complicated technologies, and we've been part of developing a lot of the complicated technologies. And one of the most attractive things about this ViewSite Brain Access System is that it's so simple. It is made out of polycarbonate resin, which allows for the visualization of the underlying brain tissue because it's clear plastic. Sometimes, like I said, it's the simpler things that are overlooked. So when the doctors see it, their first reaction is, "Wow, this is great. How come nobody else thought of this?" And that's just it — because it's a simple device.

"In the beginning, it was friends and family with us, and those friends and family are still with us."

TWST: Now that it's about a year into commercialization, how have sales been going?

Ms. Vinas: Sales have been good. The only unfortunate part about the situation for us is that for the majority of our existence since 2005, it's been just Ken Coviello and me. It's just been the two of us at the helm, working on the actual development of the VBAS, the FDA approval process, ISO Certification to 13485:2003, CE marking, HPB licensing, getting the SLA prototypes out there for field input, getting the clinical evaluations and formalizing business plan for the company. And in 2009, under the 2008 larger investment that we've received into the company, one of the stipulations is that the company had to file an S-1 and go public. So in February 2009, the company's S-1 was declared effective. That happened to be the same time that Wall Street crashed and it became a very challenging time for us to overcome. But we really bunkered down, and we stayed with it under the belief that we are doing the right thing. And this is a company that makes sense, and it just needs to hang on for a little bit longer. And then something big is going to happen to allow us to carry out our vision, and that's exactly what happened.

In December 2009, a good 10 months after we went on a survival budget and curtailed marketing activities, Fountainhead Capital recapitalized the structure of the company, converting our debt to equity and committed funding under terms outlined in our 8-K. They wound up taking off about $1.1 million of the company's debt. We're very excited about that opportunity now; we can get out there and do what we know how to do, to grow and promote this product line, and then expand that same talent into growing the company into other areas. Our plan for the VBAS is to increase clinical publications, explore new models, explore the feasibility of image-guided surgery integration and look for additional opportunities within the neurosurgical field for growth potential.

TWST: So they own 85% of the shares?

Ms. Vinas: Yes.

TWST: What's the rest of their role? It sounds like they're involved in running the company as well?

Ms. Vinas: They don't run the company. We have a board of directors. I'm the Chairwoman of the board. My partner, the CEO of the company, is also a Director of the board. Fountainhead has two director seats, and then we also have two independent directors on the board as well. Management runs the company and is governed by our board of directors. They're not coming in saying, "We come from the medical device manufacturing background, and we can do what you do." It's quite the opposite. They're saying, "We believe in you as management; we believe in your technologies that you have. We're a majority shareholder; we're coming to you saying that we're going to do what we need to do as Fountainhead Capital Partners, so that you can go out and effectuate your business plan." And that's exactly what's happening.

TWST: So eventually, you would see more shares being available on the open market?

Ms. Vinas: Yes.

TWST: Any idea what the time frame is for that?

Ms. Vinas: I do not have any time frame on that, but everything that we do here internally is working on the promotion of making that become a reality in the near term. I will tell you that we're very focused on building the credibility of the company, and that in turn should create the drive and the value-add for the shareholders of the company and any new shareholders that want to come into the company.

TWST: How would you describe the outlook for the industry in general and for your company in particular right now?

Ms. Vinas: I think there are a couple of variables to consider. One is the obvious health care reform and the bill that they're approving. I think it's too early a stage to make any full assessment from that. Everybody is trying, even doctors. I have many surgeons that are my friends, and they share with me that these laws that they're trying to put into play do not take into consideration the surgeons' outlook on it, which is their liability insurance and their premiums that go up, and their restrictions on what they can do and what they can't do. So there's just a lot of things to take into consideration. And one of the things that we want to do is keep our nose to the grind and give products that add value.

What I'm working on now is a cost-benefits analysis to share with the hospital administration boards. Our devices were designed to add value — not only to the surgeon and the patients, but also to the hospital, by promoting beneficial procedural outcomes, which allows for the patients' length of stay to be shortened and which cuts down on the OR time, creating a more efficient and more effective procedure to be done by just one simple device. That's something that is underway right now. Our whole notion is to get out there and build the credibility of the company with clinically viable and acceptable products that make sense and that add value to the surgeons, procedure, the hospital and certainly the patients. So the outlook that I believe is that everybody needs health care and health care can work for everybody. Right now, we are working on one small part of the equation and are hopeful to continue adding products that just make sense and serve a multipurpose function. It's definitely something that's at the forefront of our desire as a medical device manufacturer.

TWST: Since you are also involved in several international markets, are you more focused on the U.S. or abroad?

Ms. Vinas: Our primary focus is in the U.S. because the U.S. is still the largest market. But we also didn't want to turn down the opportunities to get things started overseas. So we recently signed an agreement with a large medical device company, a distribution company called Devon International, for China and South Korea. We also have distributors in Italy, in Greece and Spain. We also have evaluations in several other countries, including the Benelux countries as well as in Switzerland, too. Again, there's just the two of us that are really driving this as management, and we like to make sure that we are staying focused on the priorities and staying focused on the growth of our one product line right now, and making sure that we are successful and focused, one strategic step at a time.

TWST: When you announced the completion of the recapitalization in a press release, there was something in there about intentions to make acquisitions. I was curious about that side of the equation.

Ms. Vinas: One of the things that we're privy to, being that we are a young medical device company and that we have been in these industries for collectively over 35 years, we can see a good product. We don't necessarily think — because we've been in this position with Vycor Medical — that just because the company runs out of funds or runs out of that opportunity to get funded, doesn't mean that they don't have a great product line or technology. So we're seeing that as Wall Street actually begins to recover and as the health care issue comes up, that more and more medical device pioneers are unable to fulfill the next step for their own growth. So there's industry-focused shows that we intend to keep an eye opened for these opportunities. We have always put our feelers to figure out, okay, well, who is doing what? What's going on with that? We have doctors that come to us all the time that say, "Hey, what do you think of this idea?" And being that's how I founded Vycor Medical to begin with, we pursue these opportunities by saying, "Let's sit down and meet, and go over that idea that you have." There are companies out there that might get into a cash-strapped situation like we did, or somebody else that has this great idea, but either they are looking to retire or they don't know what to do with their idea. This is what we are looking for, and where acquisitions and mergers is a possibility. Going forward, we anticipate getting the attention that we deserve by the other large medical device companies. We're absolutely looking into every possibility that comes our way because we would be foolish not to. Our focus right now is on the existing product line and growing that with new devices, clinical publications that focus on the clinical efficacy of the VBAS and the cost savings of VBAS, and image-guided surgery integration.

"As of December 2009, we had over 800 surgeries that were carried out utilizing the VBAS, with over 50 U.S. hospitals that have approved our product for use and actually purchased the product."

TWST: What about investor relations? Do you give a lot of attention to that?

Ms. Vinas: We work with Fountainhead Capital Partners on that aspect of it because of their strong background in the investment banking industry.

TWST: Do you feel your are getting the word out to potential investors who might be interested?

Ms. Vinas: Absolutely — and everything needs to be strategically.

TWST: What might be some year-by-year milestones or indicators that investors should watch for as they keep an eye on Vycor?

Ms. Vinas: I would say first and foremost is an increase in our sales, and that we're coming out with new devices that the market is seeking and that have clinical acceptance, clinical publications of the company's product line. I'm going to tell you that I'm going to work on setting the foundation back to the fundamentals — rebuilding the credibility of the company, since 2009 was such a financially hard year for us; building up our distribution network, so that you're going to start seeing a lot more of Vycor Medical and the VBAS in many other institutions; and having that clinical acceptance and those publications that these major institutes want to affiliate their name with our company and our product line.

TWST: What would be the two or three best reasons for a long-term investor to take a look at Vycor?

Ms. Vinas: One, that we are a company that has a simple technology that makes sense and that it is a platform technology for future growth. We even have a therapeutic application that we're looking into. You also have the commitment from management of making this product a success. In the beginning, it was friends and family with us, and those friends and family are still with us. So it's something that we carry very near to the heart. It's something that's a dream come true for me because it's an idea that I saw as a sketch on a napkin that I was able to take to a commercially successful product. When you say, "What is success?" I don't look at success in this instance as "I've got $10 million in the bank from this endeavor." I look at success as "I've got right now over 800 surgeries that were performed and every reported surgeon said he got great surgical results." I added value to that patient's life and that, to me, is a success story.

TWST: You said that this all started as a two-person company. Tell me a bit about the leadership.

Ms. Vinas: Again, the areas of expertise. In the beginning, we just said, "Let's not try to reinvent the wheel here. Let's use our expertise in the manufacturing side of medical devices, and go and find a world-class manufacturer that's in our backyard that we can work with. Let's take my expertise in regulatory compliance, quality assurance and business development, and do what do we need to do first." So that's the ISO 13485:2003 Certification. Essentially, we were a virtual company in the beginning and yet, here we are, establishing an ISO-certified system to a 13485:2003. We put a total quality management, TQM, system in place. It allows us to have defined standards in place to allow us to grow both internally and externally. We then received our U.S. FDA 510(k), our CE marking and Canadian approval with my expertise. Ken's expertise is manufacturing and running everything lean and mean on what we call the "shoestring budget," which we would laugh about. We put everything we had into this company because it's a company that we absolutely believe in, and we are convicted to this cause. Our expertise is well defined and evident, but we feel that in order to ensure we have covered all of our bases, we bounce ideas and concepts off of one another. It is our own little network of checks and balances to make sure that we've got everything right.

TWST: Anything else you wanted to touch on?

Ms. Vinas: I think I pretty much said it all. For now, it's just that I'm very excited about the opportunities and the future of the company.

TWST: Thank you. (MJW)

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