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A Focus on Smaller Medtechs Ahead of Growth Curves

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BROOKS WEST is a Senior Research Analyst who covers medical technology at Craig-Hallum Capital Group LLC. Mr. West is a certified member of the Minnesota Medtech Mafia, having worked at a senior level in the industry with a number of high-profile leaders of medical device companies. He leverages a large network of industry and physician contacts to bring a deep, ground-up approach to his coverage universe. Previously, he spent more than 10 years in investment banking, venture capital and investment management. Mr. West holds a B.S.B.A. from the Boston University School of Management.

SECTOR — HEALTH SERVICES

(ABT806) TWST: What is the supply and demand balance like at the moment for both the patient and hospital segments of the medical devices industry?

Mr. West: Let me start with patient demand. It appears that patient demand certainly fell off in the first half of the year versus what we saw crescendo into Q4 of last year. I would point to all the macro issues that people are talking about in terms of joblessness, people coming out of COBRA, higher deductible insurance, the whole thing. We saw that continue with the major private insurers when they reported their Q2 numbers. You're continuing to see people come off the commercial portions of those businesses. You roll that forward in combination with hospitals continuing to try to manage inventory — I don't know whether there is another massive inventory reduction to be had — but certainly hospitals are managing inventory levels. This phenomenon that we're seeing of hospitals acquiring physician practices, that is starting to trickle down to maybe the next level of surgery centers or similar-type facilities that might have historically been able to have a little bit more leeway to buy versus the hospital markets. It is tight out there; everybody was concerned coming off of the **Medtronic** (MDT) call a few weeks ago that things have gotten significantly worse from June into July and into August. I think it's too early to call the whole ball game based on what **Medtronic** said. We just got off of the **Patterson Dental** (PDCO) call, for example, and they said demand is remaining fairly stable. They actually see some evidence of a potential pickup in the second half of the year. So I think there is maybe an overreaction here post-**Medtronic**, but we'll get a chance to do more field checks and hear from more companies at conferences in September.

Highlights

Brooks West discusses his coverage of the medical devices industry. The analyst outlines key issues affecting the space, including elevated unemployment rates, COBRA expiration and higher deductible insurance. Mr. West focuses on Medtronic, explaining the negative effects of the company's most recent earnings call on the medtech space. He recommends investors pay attention to smaller companies with unique technology, as larger companies with legacy portfolios are facing increasing pricing pressure. While the sector remains out of favor, Mr. West sees opportunity in several stocks. Companies include: Medtronic (MDT); Patterson Companies, Inc. (PDCO); Conceptus (CPTS); AGA Medical Holdings (AGAM); American Medical Systems Holdings (AMMD); ArthroCare Corporation (ARTC); NuVasive (NUVA); St. Jude Medical (STJ); AngioDynamics (ANGO) and Hologic, Inc. (HOLX).

TWST: Do think people may be taking Medtronic's issues and extrapolating them into an industry trend?

Mr. West: I think that's the case, and I think in some cases it's fair because, for example, in CRM, **Medtronic** has 50% of the market; in spine, **Medtronic** has 50% of the market. But you have to overlay some specific problems at **Medtronic**, including in spine, in particular, a recent reorganization of their business there. And so you have to somewhat question how accurate was the data that was coming to them when they were giving their guidance at their June analyst day and then updating their guidance at a conference later that month versus their performance. They are also struggling from a general lack of new products, and on the cardiology side, or CRM side, they've been hung up with a warning letter. In spine there have been continuous reorganizations going on for really the past three

years, along with an undifferentiated portfolio.

TWST: As you mentioned, unemployment still remains high and insurance levels are down. Do you expect any specific outcomes for the industry now that health care reform has been approved?

Mr. West: I think the bigger issue is the economy versus the health care bill, specifically for device companies. I don't think you're going to see a big impact from the bill in medtech until 2013-2014. I think the bigger issue is just joblessness. Until people have insurance, they are not going to get these procedures. And if you need a major clinically "unelective" procedure, you're going to figure out a way to get that done, but you're certainly going to try everything else first.

"I think the bigger issue is the economy versus the health care bill, specifically for device companies. I don't think you're going to see a big impact from the bill in medtech until 2013-2014. I think the bigger issue is just joblessness."

TWST: I think many companies now, when they hire staff, they put employees on probation from insurance for something like 90 days.

Mr. West: Yes, and that's been around for a long time. But you're right, there certainly could be a lag in terms of people getting insurance. But I think at the same time, if you're confident that you have income coming in again, you're more likely to go out and get a procedure — call it a peripheral vascular procedure or something you can't put off for a number of years — but you might put it off until you get your next job. But it's a fair point. A number of us who cover these stocks have remarked, as we overhear our colleagues who cover tech stocks, that people seem to be willing to go out and buy the new iPhone or iPad, but they are not going to the doctor; women are not getting their PAP or HPV tests. And that's what seems to be what people are choosing to do right now.

1-Year Daily Chart of Medtronic

Chart provided by www.BigCharts.com

TWST: That's a very interesting point: consumers' disposable income might be going toward something else.

Mr. West: Another thing we were talking about this morning — **Children's Hospitals**, here in Minnesota, making a comment that due to a significant increase in the number of pediatric patients going onto Medicaid insurance that they were having to lay off 200 to 250 people. That's because you only get paid 80% of the dollar at cost to treat those patients. Some of what might be coming through the system right now is more and more people on federal programs, and you specifically look at Medicaid and might that be having an influence down the line in terms of the types of procedures that are under pressure. It's hard to tell at this point.

TWST: Would you say California is a place where medical devices are quite down in terms of consumption due to high unemployment there?

Mr. West: Perhaps, you go back to the trends we talked about with joblessness and what types of insurance people have, but at the same time we follow a company called **Conceptus** (CPTS) who has a big portion of its California revenue base from Medicaid, and they seem to be able to have very robust reimbursement, and they've maintained price. So it really is kind of a case-by-case scenario.

TWST: What's going on in terms of capital spending?

Mr. West: It feels like it's stable. I think it's going to be interesting because hospital capital spending is driven by budgetary cycles, which end in June and December. It feels like again it's somewhat stabilized at a reduced level from Q4 of last year, but we won't really start to get those checks until mid to late September.

TWST: Are there any companies currently developing innovative products that give them a competitive edge in this difficult environment?

Mr. West: You've raised a good point because especially coming off the **Medtronic** call, our clients were calling and saying, "Hey, how do we play the themes that appear to be emerging?" Let me give you the themes that we're seeing and then we can go into how to play those trends. Clearly, a concern coming off the **Medtronic** call — that procedure volumes fell off in late June into July and August — was in terms of how has this trend reversed itself or what might cause this trend to reverse itself other than a pickup in the macro economy. The other themes: Number two, legacy commodity products are clearly suffering at the hands of differentiated technology, which gets to your question. But where we're seeing price pressure, where we're seeing companies refer to problems with mix, it's where they don't have a fresh product. This is whether they're trapped behind FDA approval, or whether they just haven't been getting things out of the R&D pipeline. Those are the places where we're seeing price pressure. And then thirdly, on the hospital and physician demand side, in some cases hospitals are buying physician practices try to impose more purchasing rigor and to focus not only on the clinical benefits of a particular therapy but also the economic benefit of that therapy. So I think those are the big themes we're dealing with.

Then I think you have to look at the stocks. We are recommending stocks with differentiated technology or which are entering significant new product launch cycles, specifically pointing out those who have already gotten things through FDA, as clearly the FDA approval process has slowed down. So we like **AGA Medical** (AGAM); we like **American Medical Systems** (AMMD), **Arthro-**

Care (ARTC), **NuVasive** (NUVA) and **St. Jude** (STJ). The other kind of theme that we're playing is, and we talked about this in the last interview, I think you're going to see an acceleration of the rollup, so to speak, of small or small-cap medical device companies by the large diversified companies who are trying to find growth and who are sitting on a bunch of cash. To play that rollup theme, own dominant niche players, which represent good standalone investments but that are also likely acquisition targets. A lot of names that were mentioned earlier overlap here — **AGAM**, **AMMD**, **AngioDynamics** (ANGO), **ArthroCare**, **Conceptus** and again **NuVasive**. Lastly, we're avoiding stocks tied to elective procedures or that have significant pre-FDA approval pipeline conversion risk.

"One company in particular that we follow, Hologic, which we think has spectacular potential multiple expansion tied to the next capital equipment cycle, with limited downside risk, does in fact have a big FDA hurdle with the potential approval of its 3D tomosynthesis system."

TWST: What would those stocks be? You mentioned Medtronic — I don't know if that would be in that category.

Mr. West: Medtronic has got multiple issues, but they are hung up with FDA on the Mounds View facility warning letter that's causing them to not be able to get the new CRM products through.

1-Year Daily Chart of Hologic

Chart provided by www.BigCharts.com

TWST: Are there other companies you're avoiding?

Mr. West: We have chosen not to follow companies that are heavily dependent on elective procedures, companies focused on aesthetic surgery, for example. Most of our companies have done a pretty good job of getting products through the FDA. One company in particular that we follow, **Hologic** (HOLX), which we think has spectacular potential multiple expansion tied to the next capital equipment cycle, with limited downside risk, does in fact have a big FDA hurdle with the potential approval of its 3D tomosynthesis system. That's one that's causing people to take a pause in looking at that stock.

TWST: Do you have any "sell" ratings now?

Mr. West: We don't have any "sell" ratings. We obviously get asked about that all the time. I don't have anything that has a "sell." We did have some caution on some stocks that we picked up coverage earlier of in the year, specifically picking up the trends of low patient volumes. We saw that at **Hologic**; we saw that at **Conceptus**. Those stocks have washed out to levels where we have upgraded them to "buys." I don't have anything that we currently cover that's a "sell."

TWST: As you speak with management teams, what are their levels of confidence?

Mr. West: I think the management teams are conditioned at this point to speak with cautious optimism. For the teams that continue to be most optimistic on their businesses, I'd point to **American Medical Systems**, I'd point to **NuVasive**, and I'd point to **St. Jude**. I think the rest of the management teams, at this point, they are going to say, "Hey, we are cautiously optimistic." But everybody points to the necessity of new, differentiated products. You have to have a cadence of new products to be able to compete in these markets and hold up against the tough macro. If you are weighed down by a legacy product portfolio, those are the management teams that are talking about price and mix issues, and aspiring to have a portfolio of new products.

TWST: What is investor interest like at the moment?

Mr. West: We keep thinking it can't get any worse and then it keeps getting worse, but the medtech sector must be close to bottom in terms of sentiment, which probably means too much negativity is now priced in.

TWST: But then again how are iPod sales going?

Mr. West: You are right — exactly. Not to take a swipe at our technology colleagues, but people are very cautious on these medtech stocks. The health care specialists are the core audiences for these stocks; there is not a lot of interest in the generalist population. Even as a traditional defensive category, given concerns about government, given concerns about the health care plan, given concerns about the labor market and just the potential for one of these stocks to significantly move one way or the other based on an unforeseen event, it is something that a generalist investor maybe doesn't quite understand. So the sector remains out of favor; perhaps that points to opportunity as the stocks have all come in especially recently.

TWST: It's not just about the sale of medical devices; there are all these additional expenses one incurs before getting to the point of buying a medical device. Many times, these expenses are actually much higher than the cost of one specific item.

Mr. West: Absolutely. The revenue that is attributed to these companies is influenced by multiple government agencies. There is not consistency across the private payers in terms of how they reimburse for these procedures, and then you have to analyze the underlying technology. So these are very complex stocks.

TWST: Is there anything else you would like to add?

Mr. West: I am looking at a recent e-mail that we sent out to clients, but it's really the three themes that are emerging post the **Medtronic** call and how we would play these trends is our continued focus. We continue to worry about potential changes to FDA and the 510(k) process, which we talked about last time. But I think you get a sense about what's going on. The thought I would leave you with is there are some very good stocks out there that are

sitting in front of growth curves which are going to power through this environment, and those are the stocks that we talked about earlier in this conversation that you want to own.

TWST: Are there other companies aside from the ones you've already mentioned that investors should keep an eye on?

Mr. West: I will just give you the tickers, **AGAM**, **AMMD**, **ANGO**, **ARTC**, **CPTS**, **HOLX**, **NUVA** and **STJ**. Obviously, skewed towards small cap, but that's a nice collection of stocks that are either niche defensible businesses or that are sitting in front of those growth curves that we like.

TWST: Thank you. (MRR)

Note: Opinion and recommendations are as of 08/26/10.

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In a Stock Picker's Medical Device Market, Smaller is Better

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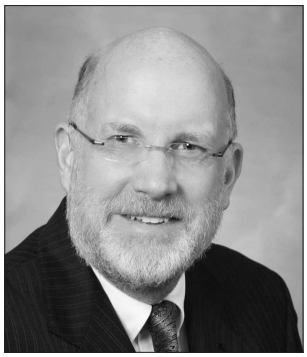

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SECTOR — HEALTH SERVICES

(ABT805) TWST: What does the industry look like right now, given the state of the economy and also the lack of implementation of a health care system?

Mr. Gunderson: The economy is new and different than what it has been before. Health care as an investment vehicle has historically been, consistently been, a defensive sector, such that when the economy goes down there are certain items that will be more in demand by investors simply because you can't do without. You need gas for your car, you need cereal for your breakfast, you need health care for your family, and that's the way it has been until this latest recession hit. What we're seeing is lower demand, lower utilization. Is it related to unemployment? No, many of the unemployed keep their insurance. What it seems to be related to is the medical insurance copays. Between the two last recessions, the copays that people have to pay on their insurance have gone up significantly so that now it's a real economic choice, it's a real financial choice. It's a budget choice of whether you go to the doctor and pay anywhere from a $20 office visit copay or a $2,000 surgical procedure copay, and that you are making that decision based on your own budget as opposed to "other people's money." We started to see this phenomenon start to play a major role in personal health care decision-making in late 2008 and then into 2009, as people were going to the doctor less frequently, their prescriptions that were filled were down and the number of medical procedures were down. Can you postpone a cosmetic surgery if the budgets are little tight? Absolutely. A facelift, a nose job, something like that is more in the retail zone. But what we're seeing now is people are starting to postpone some of those other more chronic disease treatments, where you are deferring getting an artificial hip, getting an artificial knee, some are putting off heart procedures and one of the ones that I find even more disturbing is diabetes care. We have a huge, almost an epidemic of diabetes in this country and the world, and yet the sales of diabetes drugs and therapies has flattened in the last two years, and that makes no sense from a care standpoint, and it makes great sense from an economic stress standpoint. So part one, the end user of the health care system is being impacted by the economy like they haven't before because they have to pay more out of pocket and now it is becoming more of a personal budget kind of decision.

Part two is the hospitals, which are the intermediary between the stocks we invest in on the medical device side and the patients on the other side. The hospitals in 2008, 2009 and into 2010 are strapped. Their budgets are constrained, the insurance payments to them are less, and the number of lower-profit-margin Medicaid patients and nonpaying patients has increased. So the hospitals are as economically strapped as they've been in years and putting pressure on the device companies to share some of the pain in form of pricing decreases. On one hand, you've got less demand from potential

Highlights

Thomas Gunderson discusses his coverage of several medical device companies, pointing to lower demand and lower utilization as the most worrisome trends in the industry. Given this difficult macro environment, Mr. Gunderson recommends smaller device companies with unique products that address "non-deferrable" medical conditions. The analyst advises investors to take advantage of this stock picker's market to find single companies that will outperform rather than a broad basket of medical device stocks. Companies include: DexCom (DXCM); Volcano Corporation (VOLC); Cyberonics (CYBX) and Cutera (CUTR).

patients, and on the other hand, you have your main hospital customer in dire financial straits.

TWST: What are your thoughts on the physician space?

Mr. Gunderson: On the physician side, if you have fewer office visits and you are doing fewer procedures, then the physician is being paid less than before. But the pain hits a little differently for physicians. In past years pre-recession, hospital profits were being augmented by their endowments. When the stock market went down, those endowments went down and the profits from those investments went down as well. In many cases, hospital profitability was significantly dependent on investment profits. Now with the stock market decline, many hospitals are now in the red. Do the doctors' investment portfolios go down? Yes, but it has not impacted their businesses as much as it has with the hospitals. But separate from financial issues, the majority of physicians are still busy and in some cases starting to deal with patients that are more advanced in their disease state due to the medical treatment postponement that we were discussing earlier.

"Some medical problems are more difficult to postpone treatment; the companies that treat these 'non-deferrables' have performed relatively better in the recession."

1-Year Daily Chart of Cyberonics

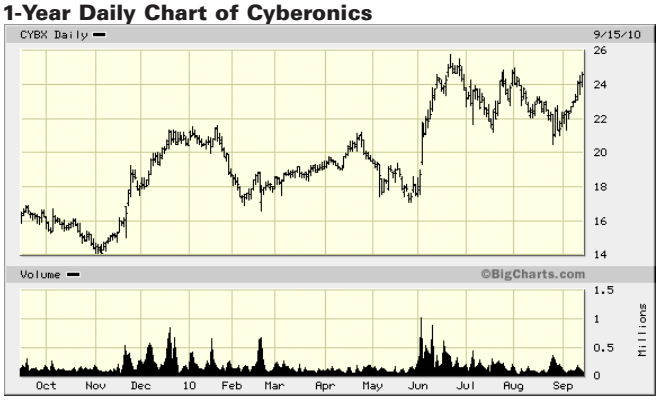

Chart provided by www.BigCharts.com

TWST: Which companies are weathering this difficult environment well at the moment?

Mr. Gunderson: There are some; they are mostly smaller ones that have unique products, that are in the growth mode right now, and so the recession is having less of an effect on their stock valuations. Certainly the recession had an impact on the earnings multiples for virtually all medical device stocks, but even despite some economic headwind, the growth for these select companies is still pretty good and the stocks are doing well. Which ones would that include? It would include names like **DexCom** (DXCM), where they have a new continuous glucose management product for diabetics to use at home that is growing significantly, more than doubling in revenues over the last year, and the stock is up over 300% since early 2009. Another company with good solid growth in the recession is **Volcano** (VOLC). **Volcano** has done well with a new technology that is converting the old technology of imaging the inside of a heart's artery using ultrasound. Ultrasound inside the artery has been used for decades, but what **Volcano** has done is made it easier, simpler and more cost-effective for the hospitals to use the product. They have been growing nicely both in the U.S. and in the rest of the world, particularly in Japan. **Cyberonics** (CYBX) is another company with a single product that seems to be doing well. **Cyberonics** has an implantable medical device for the treatment of epilepsy. Having uncontrolled seizures, seizures that cannot be controlled adequately by drugs, seems to me to be a difficult ailment to postpone. Disruptive, drug-refractory seizures is not one of those medical problems that is usually going to be linked to one's monthly budget. Uncontrolled seizures are more in the same category as a broken bone. If you fracture a bone in an accident, you don't look at your bank statement to see if you can afford to fix it this month. We think it's the same with epileptic seizures. Some medical problems are more difficult to postpone treatment; the companies that treat these "non-deferrables" have performed relatively better in the recession.

TWST: Conversely, are there any companies that you don't think are handling the recession well? Any companies for which you have a "sell" rating?

Mr. Gunderson: Yes, it's been very tough. I mentioned it before on cosmetic surgery. It's been very tough for the aesthetic companies. They in many ways respond more like a luxury consumer company and their procedures are more easily deferrable. So many of the aesthetic laser companies have suffered in the recession. The prospective patients or prospective consumers just haven't been coming in for the procedures. Even if the economy starts to rebound and they do come into the physician's office, the doctors who might buy these lasers are reluctant to commit to a $100,000 purchase. So growth has declined significantly in the aesthetic laser sector. The only company I cover in this aesthetic zone is a name called **Cutera** (CUTR), but the whole sector has been hit and recovery will be slow.

TWST: Is that how you would advise investors to approach the space right now, by looking at particular products that make a company stand out?

Mr. Gunderson: Yes, I would. I think it has become more of a stock picker's market. Probably across the board in other sectors but certainly in med-tech, the large-cap companies, the multinationals, the ones with several businesses and scores of products within those businesses have not performed well so far this year. Partly it's the overlay of the economy in the U.S., which I've been talking about predominantly here, but then there are the global issues that are also having a dampening effect on earnings. The larger companies are facing the difficulty of growing large numbers; the performance of the larger companies has not kept up even with the average Standard & Poor's 500 company over the last 12 months. So in the wake of not being able to invest in those

historically safer, big portfolio companies, which stocks have performed? It have been the ones that are smaller, maybe more adroit, but perhaps most likely it's the ones that have the right product at the right time, and that sole product can have an impact on the bottom line. Investors see that positive impact and the rewards have been relatively strong, even in these economic hard times. Do the big companies have new products that are in the right place at the right time? Yes, they do. It's just that they're so big, one product cannot have the same kind of impact on the bottom line.

TWST: As you talk to management teams, currently what's their level of confidence in the market in general?

Mr. Gunderson: It's better than last year, but it's not good yet. We're starting to see some improvements in the big picture. Are there more patients coming in? One of the things I said earlier was that patients had been deferring elective medical procedures. While you can defer having a meal at a fancy restaurant, you can defer buying a car, or an appliance or a new house, it is difficult to defer your health problem indefinitely. Many medical conditions are progressive; they will just become worse and worse over time. Eventually the problem has to be dealt with, but you can defer it for a while. Last year we saw what I would say is the trough in that procedure demand, and the decline in demand has been easing now, according to our conversations with managements. Patient demand has been coming back a little each quarter over the last three or four quarters, but we have not yet returned to where we were three years ago. And how is that being measured? There are not really any real-time data that we can assess, so we look at some of the public hospitals that report, and they're starting to see a few more procedures. We look to companies that make sutures. Sutures are used in almost any procedure, and the suture market is starting to come back, growing maybe 2% to 3%, but again not back to where we were. The short answer is it looks better, but not good yet. There will be ebbs and flows in patient demand as in thrall to the ups and downs of economic recovery.

TWST: What are you advising investors to do at the moment? Are they concerned about the space?

Mr. Gunderson: They are definitely concerned about the space. There are times when you can look at the health care sector or medical device sector and just invest in an index; you can invest in a broad basket of companies and do well because the sector is doing well. We're not in one of those times. So what I am advising investors to do is what I mentioned before — it has become more of a stock picker's sector and you have to look specifically at each and every company and find the one, not the group, but the one that will outperform. So we're looking at those. Given that the outperformance over the last 12 months is coming more from the smaller ones than the larger ones, we are looking more at the smaller companies. The downside to that is they are not as liquid.

TWST: Thank you. (MRR)

Note: Opinions and recommendations are as of 08/30/10.

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Predictions of a Medtech Buy Rally

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

DR. SEAN LAVIN, M.D., is a Senior Analyst who covers the medical technology space. He joined Lazard Capital Markets in March 2008. Prior to joining Lazard Capital Markets, Dr. Lavin was a sell-side Analyst at Oppenheimer & Co., where he covered medical devices and diagnostics. He focuses on minimally invasive devices and those which he believes can change the standard of care. Prior to joining Oppenheimer, Dr. Lavin worked as a Surgical Resident at Mount Sinai Medical Center, in Miami Beach, Fla. While there, he 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 the Ohio State University College of Medicine and a B.S. in chemistry with a minor in biology and a concentration in economics from the Massachusetts Institute of Technology.

SECTOR — HEALTH SERVICES

(ABT803) TWST: What is your take on the economy and on the medical devices sector?

Dr. Lavin: My overall take is that the sentiment on Wall Street, which is extraordinarily negative on at least medical devices, is probably more negative than what we're actually seeing in health care services and procedures. So we've certainly seen a bit of a slowdown in certain areas, such as spine surgery, which has certainly slowed down a few percentage points, some of the cardiac rhythm management names and the ICD space has slowed down a few percentage points, but I would say with the Street taking 20%-plus off of each of the related stock prices, this has far more than adjusted for the market slowdown with the economy.

TWST: How great of a percent have they taken off?

Dr. Lavin: A number of the stocks I cover are down 30% from where they were three or four months ago, and that is based on procedures. The spine market has probably slowed from 8% growth to maybe 4%, and the ICD market has slowed from maybe 5% or 6% growth to maybe 3% or 4%. So these pretty big adjustments to stock prices are relatively small adjustments in actual procedure volume. I think the other thing is the timing. The sentiment is that a number of the very large companies — companies like **Medtronic** (MDT), a company like **Stryker** (SYK), for instance — have some product lines that are going on 7 or 8 years old in spinal surgery, in ICDs. Because that's the only company that had kind of subpar quarters, recently competitors have launched new products — if you look at companies like **St. Jude** (STJ), that has a new ICD out this year, **NuVasive** (NUVA), that has a new lateral approach on spine products out in the last couple of years. And so I think we may be hearing a few more excuses on reimbursement and procedure volumes from some of the very large partners, saying that some of their products have been a little old and because investors really focus on the larger players rather than about the whole space now.

TWST: Are there any other companies with innovative products in development that will give them a competitive advantage?

Dr. Lavin: I think the four product areas that are going to grow double digits in the next five-plus years

Highlights

Dr. Sean Lavin offers his outlook for the medical devices space, highlighting the four product areas he predicts will see double-digit growth over the near term. Dr. Lavin believes Wall Street may have negatively over-adjusted medical device stock prices to compensate for the economic slowdown. Given these companies' low valuations, he sees investment opportunity with little risk over a two- to three-year horizon.

Companies include: Medtronic (MDT); Stryker Corp. (SYK); St. Jude Medical (STJ); NuVasive (NUVA); Intuitive Surgical (ISRG); Edwards Lifesciences Corp. (EW); Johnson & Johnson (JNJ); Thoratec Corp. (THOR); HeartWare International (HTWR); Varian Medical Systems (VAR); Endologix (ELGX); Sequenom (SQNM); Abiomed (ABMD); Masimo Corporation (MASI); Gilead Sciences (GILD) and Amgen (AMGN).

are robotic surgeries, which is **Intuitive Surgical** (ISRG), and they are a monopoly, and transcatheter valves, which are from **Edwards** (EW) and **Medtronic**. It's certainly too small of a portion of **Medtronic** to really set that company apart, but for **Edwards** it's been a differentiating product. Then you have the left ventricular assist devices, or LVADs, which include **Thoratec** (THOR) and **HeartWare** (HTWR), and that market is growing 30%-plus. The atrial fibrillation market is still growing 20%-plus, but that's dominated by **J&J** (JNJ) and **St. Jude**, and it's probably not a big enough product line to move those things.

TWST: Do you approach the physician segment differently than you do the hospital segment?

Dr. Lavin: Certainly I look at every device from both aspects. Generally the hospitals are the ones collecting the payments on most procedures — most of these are open-heart surgeries — and hence they fall under the DRGs. Physicians, up until now and I think going forward, will have a lot of say in how that's used, which is why hospitals have had a difficult time pushing back on price. If a surgeon or an interventional cardiologist wants a certain device, he wants that device, and if he's not given it, he can go elsewhere. Over the last few years, we've seen more and more physicians becoming hospital employees. As the economy turns downwards, it becomes harder to run a single practice. Physicians have signed contracts, and if that happens, the hospitals will get more power, and hospitals can do more to tell the physician what products they are going to use. That allows the hospitals to push for cheaper props.

"I don't know what's going to happen in the next few months, but I think it's a very safe space to invest in now if you have a two- or three-year horizon. Some of these companies, like* Medtronic*, are so cheap on a valuation basis, they're trading at just about eight times their cash flow."

1-Year Daily Chart of Intuitive Surgical

Chart provided by www.BigCharts.com

TWST: What about capital spending trends? Are hospitals more likely to have less capital available for things like investment in medical devices? Is that a problem?

Dr. Lavin: It has certainly slowed down some purchasing. I would go back to it, it's very small percentages — 2009 was probably the worst economy we've seen, at least for hospitals, in a long time. And capital spending in 2009, also including big machines, little machines, etc., was down about 8%. So if you were to talk to many people investor-wise, you'd think it was down a lot more than 8%. But 8% is a big number because it usually moves 1% or 2% over a year. So this year, it's back up about 5% as far as I can tell so far in the first half of the year. And once again, that's a pretty big number, considering a normal year might be 1%. And so we've kind of lost two years of growth — we're not really much below that 2007 number on capital spending at this point. The question becomes what happens next year? There are people who think that capital spending will stay as it is — I am probably in that group — that it is going to be relatively flat, and that's what we're hearing from hospital CFOs. There were other people on the short side; they think that Europe is falling apart and that we're going to see a pretty significant slowdown around the world.

TWST: Are there any stocks you're really positive on at the moment?

Dr. Lavin: I'm very positive on **Intuitive Surgical**. I'm very positive on **Varian** (VAR). I'm very positive on **Endologix** (ELGX) and **HeartWare**. They are probably my top four choices right now.

TWST: Conversely, are there any stocks you are worried about or consider "sells?"

Dr. Lavin: I don't have a "sell." I have some concerns based around a number of competitors entering the space and pricing in the buy market. That's probably what I have the most concerns around. I think **Medtronic** is a "buy," and I think it's undervalued, but I have concerns about their end markets that are declining.

TWST: What are the concerns of the management teams with whom you've spoken?

Dr. Lavin: I think they probably have two major concerns. One is nobody knows what — we didn't have a patient slowdown in 2009, but we've had a pretty big capital spending slowdown of about 7% or 8%, and there are talks that European governments are going to do that again in the future. And so I think there is concern there that it's very good sales outside the U.S., and there is chatter about government spending decreasing. I think the other thing they're concerned about is how this health care reform is going to be implemented in 2013. There is certainly a positive for some companies that are going to have more insured patients, but there are two negatives. One is the medical device tax; it looks like it may go into effect then. And the other one is the fact that if the current loss stands and people pay a very small penalty for not having insurance, and you can buy insurance once you get sick, and those insurance companies can't turn down such patients, there is probably going to be a pretty large group of people who choose not to have insurance, choose to pay the fine and then choose to buy it if they get sick. That's a problem for hospitals because those patients, if they have trauma, will not pay. I think that will probably be altered by 2013 or at least by 2014, once the government is prompted.

I have spoken to several major hospital CFOs who have said that if this law doesn't change at all, every hospital will be out of business a couple of years after it goes into effect. I don't think

it's the government's intention to put hospitals out of business, so I think that either they will raise the fine for not having insurance to a level that encourages people to have it, or they will have to do something to make it so that pre-existing conditions, where somebody intentionally doesn't have insurance and still has a procedure, they're going to have to do something so that you can't buy insurance after you get sick.

TWST: Looking at current trends in your coverage group, what is your investment strategy? How are you advising investors to play the stocks?

Dr. Lavin: We've seen an overall market slowdown. If all of medical technologies were growing at 6% or 7% three years ago, they're probably growing 2% to 4% now, and that has made it very difficult to take money in the very large-cap companies. I've been advising people to look at these small- and mid-cap companies that have differentiated products that are basically monopolies in the space, and so that's where companies like **Intuitive Surgical**, **Varian**, **Edwards**, **HeartWare**, **Endologix** come in. They don't really have a competitor product as equivalent, so they are actually able to keep raising prices. And if a hospital doesn't want to buy, they can't use that device. So I've been looking for differentiated companies that don't have a lot of competitors, and I've been looking in the small-cap space because I think that a lot of these large-cap companies that aren't growing, they have built up very good balance sheets. **Medtronic** has $5 billion in cash and will make another $5 billion this year. **Stryker** has $4 billion in cash; **J&J** just raised money at Treasury rates. And so I think we're going to see some pretty active acquisitions in the small- and mid-cap space.

TWST: Are there any companies you haven't mentioned that you'd like to now?

Dr. Lavin: In the small-cap space, I guess there are a couple of others that kind of stand out. They are **Sequenom** (SQNM), **Abiomed** (ABMD) and then the other one that I've already — I guess **Masimo** (MASI) is something that I don't think their CEO will sell, but he may at some point. And these are all companies that are growing 20%-plus. They don't really have very strong competitors, so they have one competitor for pricing — it's not a big issue — and they would add growth to some of these larger companies, and the larger companies could combine sales forces and have synergies.

TWST: What is investor interest like in the space?

Dr. Lavin: It's slightly better now than it was two weeks ago. Two weeks ago, I would say it was as bad as I've ever seen in five years. There are very few generalists involved in health care right now. We saw most generalists leave before reform because if you didn't want to be a health care specialist, you might as well be somewhere else you could actually understand. They started to come back in the first quarter of this year, after the reform passed, and we saw a number of pharmaceutical companies — companies like **Gilead** (GILD) and **Amgen** (AMGN) — have to lower guidance because there were some health care reform taxes that people didn't understand. And after that, the generalists kind of got blown up on those guidance lowerings, and they have not been back. In medtech, you know, specific funds have just been very pessimistic; the sentiment is very negative and managers are also negative. I think it's gotten a little better in the last five or 10 days, as we've seen it work in the medtech market, but it's still very negative.

TWST: There's no way to predict what things will be like in a month.

Dr. Lavin: It can go either way. I don't have a strong opinion on it. One of the interesting things of all the companies I cover, all but one, I believe, hit or beat their earnings numbers this quarter. And with all but two, the stock was down. So it's kind of interesting that numbers are not really going lower except for a few companies and yet sentiment in the whole space is still more negative than the valuation, and that's a potential for a rally because at some point, investors look up and see that these earnings numbers are the same as they were three months ago when the stocks were 30% higher. I think it will start a buy rally. The question is how low do they go first?

TWST: Is there anything else you would like to add?

Dr. Lavin: The only other thing I would say is that I don't know what's going to happen in the next few months, but I think it's a very safe space to invest in now if you have a two- or three-year horizon. Some of these companies, like **Medtronic**, are so cheap on a valuation basis, they're trading at just about eight times their cash flow. And most people think seven times cash flow is a fair value for something that will never grow again, and so there is not a whole lot more downside or else these companies will go private or get lost. So I think it's a pretty safe space to invest in. Probably we'll stop for a while until the sentiment changes, but when it does, there will be quite a bit of upside.

TWST: Thank you. (MRR)

Note: Opinions and recommendations are as of 09/03/10.

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Shifting Medical Device Purchasing Trends

J O A N N E K . W U E N S C H B M O C A P I T A L M A R K E T S

JOANNE K. WUENSCH is a Research Analyst in BMO Capital Markets' Equity Research Group, where she covers medical technology companies in the cardiology, ophthalmology, orthopedic and respiratory sectors. Before joining BMO Capital Markets, she was a Research Analyst with ABN Amro (ING Barings), where she covered medical products, as well as a Research Associate in the medical technology group at UBS Securities. Her career in financial services began at J.P. Morgan, where, among other positions, she was an Associate in municipal finance investment banking in the health care and higher education group. Ms. Wuensch joined BMO Capital Markets in 2002. She holds an MPA degree from New York University and a Bachelor of Arts from the University of Delaware.

SECTOR — HEALTH SERVICES

(ABT801) TWST: Since we last spoke, how has your perspective on the medical device industry changed, given current factors such as the economy and health care reform?

Ms. Wuensch: I think in general we're in a more difficult position than the last time we spoke. In fact, we just downgraded the group on Aug. 25, 2010, to "market perform" from "outperform." In the report, we talk about multiple walls of worry — the economy, how the unemployment rate is impacting the purchasing of medical technology products, the roll-off of COBRA insurance, higher deductible insurance policies and a deferral in physician office visits. So there are multiple factors that I think are more negative today than the last time we spoke.

TWST: COBRA has run out by now for most people who have lost their jobs, correct?

Ms. Wuensch: I would assume so, or at least the ones that lost them sometime before the end of 2008 and then at the beginning of 2009.

TWST: How does health care reform come into play in this, if at all?

Ms. Wuensch: It may or may not. It may be to the degree that hospitals are anticipating health care reform and are therefore becoming even more cost-conscious than they were before. It may be that patients have heard in the press that we spend too much on health care and are changing their purchasing patterns — this theory is likely a bit more far-fetched. While there may be increased hospital maneuvering in regards to purchasing power, I think the greater impact right now is really the consumer of health care products or the individual.

TWST: Are there differences in trends between physicians and hospitals?

Ms. Wuensch: There is a trend that's not necessarily new but seems to be gaining a bit of steam, which is where the hospital is purchasing the physician practice so that the physicians and the hospital are more aligned in the purchasing product decision. We are also seeing more hospital consolidation of its vendors or manufacturers, whereby instead of purchasing products from multiple manufacturers, they may be trying to get it down to two maybe three.

TWST: What is the supply and demand balance at the moment?

Ms. Wuensch: It seems that in the first half of the year, utilization has been impacted by the adverse weather in the Northeast,

Highlights

Joanne K. Wuensch discusses several capital spending and supply and demand trends in the medical device industry, offering insight into her firm's recent decision to downgrade the space. She highlights what may be a shift in consumer spending patterns, as patients face higher copays and insurance deductibles in today's health care market. Ms. Wuensch also points to a group of innovative companies in the midst of new product cycles as favorable stock bets at the moment. Companies include: Stryker Corp. (SYK); St. Jude Medical (STJ); Edwards Lifesciences Corp. (EW); Medtronic (MDT); NuVasive (NUVA); Masimo Corporation (MASI) and Covidien plc (COV).

the lack of seasonal flu, the lack of H1N1 and the economy. Individuals are delaying physician visits, women are not visiting their OB/GYN, and we are hearing that birth rates are declining. The supply side of the equation appears to be impacted more during this economic downturn than in others, as more of the health care expense is being shouldered by the individual.

TWST: There are many steps that lead to the purchase of a medical device, including the expense of visiting a physician, follow-up visits; it's not just the cost of a procedure.

Ms. Wuensch: Correct. We are seeing individuals pay a larger percentage of their insurance copay and insurance policies that carry higher deductibles. This may be shifting the purchasing pattern cycle, as individuals may wait until year-end, when the deductible has been met, or the beginning of the year, when reimbursement accounts are freshly funded.

"Entering earnings season, people were worried about European austerity budgets and pricing. Exiting the earnings season, what people are worried about more is where have all the patients gone?"

TWST: What are the trends in capital spending?

Ms. Wuensch: Since the last time we spoke, it seems that hospital capital spending has stabilized and is cautiously returning. Yet the worry is less topical than before. Entering earnings season, people were worried about European austerity budgets and pricing. Exiting the earnings season, what people are worried about more is where have all the patients gone?

1-Year Daily Chart of NuVasive

Chart provided by www.BigCharts.com

TWST: In the U.S.?

Ms. Wuensch: Particularly in the U.S., yes.

TWST: Are people talking about the European austerity budgets any more, or is that not really an issue?

Ms. Wuensch: It is still an issue. Somewhat uniformly managements have noted that the purchasing and pricing environment is more difficult in countries such as Greece, Spain and Portugal. They also almost uniformly pointed to the European tender process whereby prices are locked in, supporting pricing as of now. When they go back to the table to renegotiate, that may change.

TWST: Are there any companies with particularly innovative products that stand out in an otherwise sluggish period?

Ms. Wuensch: I think that's an interesting question because you do have companies that are launching new products, and it appears that hospitals are still paying for innovation. **Stryker** (SYK) has just launched its new ADM X3 Mobile Bearing Hip. Several manufacturers are launching or have recently launched customized knee products, which reduce operating room time, increase the patient fit and lower the tool sets that need to be managed by the hospital. **St. Jude Medical** (STJ) in June 2010 launched the Unify and Fortify ICD devices. Sales of transcatheter heart valves (THV) by **Edwards Lifesciences** (EW) and **Medtronic** (MDT) are tracking better than expected in Europe. In September 2010, **Edwards** will present the Partner clinical data, tracking the company for U.S. approval in 2011. Finally, lateral access spine products, such as those sold by **NuVasive** (NUVA) are gaining traction. All of these devices carry premium prices and almost universally managements are saying that innovation or innovative products are still receiving premium prices.

TWST: Are there any stocks at the moment that you particularly like?

Ms. Wuensch: When we sift through the names in our coverage universe, we are looking for stocks with strong management teams, reliable growth and that are at a good value. For example, we recommend **St. Jude Medical**, which is enjoying a new product cycle in ICDs and has very good management. We recommend **Stryker**, which also has new product cycles in hips and knees, which should gain traction in the back half of this year, good management, has a strong cash position and is at a very attractive valuation. We still recommend **NuVasive**, which is sort of the best house in a bad spine neighborhood, if you will, as the market shifts towards minimally invasive surgeries. If I had to list a fourth, it probably would be **Masimo** (MASI).

TWST: Is that how you're playing the trends, trying to find companies with particular value or product cycles?

Ms. Wuensch: Product cycles, management and strong balance sheets at a good value. You can have great management but it can be expensive, and I don't think that's the best way to play today. It could be really cheap and have questionable products and a questionable management, and I don't think that's great either.

TWST: What companies are you less optimistic about at the moment? Do you have any "sell" ratings? You mentioned a downgrade.

Ms. Wuensch: We downgraded the group to "market perform" from "outperform." We currently do not have any "sell" ratings on individual stocks in my coverage universe, as the group has come under so much pressure.

TWST: Are there any other companies you are less optimistic about?

Ms. Wuensch: It's hard to pinpoint anything at this stage.

TWST: As you talk to managements, what is their

level of confidence?

Ms. Wuensch: Confidence seems to have weakened throughout the 2Q10. Companies reporting later in the quarter and into August noted that the lower utilization rates continued. It will be very interesting to see when September conference season starts and into October's third-quarter earnings, to see how volumes and utilization has trended.

TWST: What is investor interest like in this space at the moment?

Ms. Wuensch: Interest is relatively low generally. I do have investors who are looking at the names, trying to get comfortable with the longer-term earnings capacity. Many are sort of bottom-fishing, if you will.

TWST: How are you advising them at this point?

Ms. Wuensch: Similarly to what you and I just finished talking about — let's look for value, let's look for good managements, products, and let's make those bets.

TWST: Are there any other names aside from the ones you've mentioned that are good investments, or did you give the complete rundown?

Ms. Wuensch: I have a variety of "outperforms." **Medtronic** right now is particularly inexpensive, but they just delivered a really tough quarter and it's going to take them a bit to regain investor confidence. We have **Covidien** (COV), which is not in the same boat, but they too had a really tough quarter. It has really attractive valuation, but it's going to take some time to get investor sentiment back.

TWST: As we wrap up, are there any thoughts you would like to leave readers with?

Ms. Wuensch: The demographics remain very positive for this group. I think people can put off physician office visits and procedures for a period of time. The question really is how many of these procedures permanently go away and how much of it creates pent-up demand?

TWST: Because eventually these procedures will become unavoidable?

Ms. Wuensch: Right.

TWST: They will also become probably more aggravated and more expensive, correct?

Ms. Wuensch: Most of us were trained that an ounce of prevention is worth a pound of cure. But I think right now, if you can, you are choosing to delay office visits and procedures if you can in the current economy.

TWST: Thank you. (MRR)

Note: Opinions and recommendations are as of 08/27/10.

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Current Trends in Diabetes Care & Devices

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DAVID A. KLIFF is the Publisher of *Diabetic Investor*, the only investment newsletter covering the diabetes care industry. Prior to founding this firm, he was a successful Money Manager for high-net individuals. An insulin-using Type II diabetic diagnosed in 1996, Mr. Kliff offers a unique perspective on the industry due to his firsthand knowledge of living with diabetes. He earned a B.A. in speech communications from the University of Illinois.

SECTOR – GENERAL INVESTING

(ABT501) TWST: Give us a brief overview of Diabetic Investor and how you cover the diabetic market from a business perspective.

Mr. Kliff: Basically what *Diabetic Investor* tries to do is bring the perspective of a patient, because I am a Type I diabetic, into the discussion about how diabetes is run as a business. I've been publishing for about 15 years. Basically I try to provide the overall perspective to the business of diabetes.

TWST: Tell us about the latest developments in the diabetes arena today.

Mr. Kliff: I think the biggest trend that's happening right now really centers on the FDA with the Avandia controversy. I don't want to say this has turned the FDA on its head — that's probably an overstatement — but it has changed the dynamic to such an extent where it almost seems like the FDA is looking for reasons not to approve new drugs or new devices. They've become increasingly conservative in their approach, and I think some of this is an overreaction to issues that appeared in the past. In Washington, D.C., usually when something goes wrong, they throw money at it to try to fix it. Right now we're in a fairly bad economy and there are a lot of issues going on out there. It seems like with every passing day, we're getting news about either some drug recall and the FDA is really taking it on the chin, so to speak.

A prime example of this is Victoza. Victoza is a GLP-1, or glycogen-like peptide, from **Novo Nordisk** (NVO). It's a once-daily injection. The drug itself, if you look at all of the data, it works. It does a really good job of controlling blood glucose, which is the primary function of any diabetes drug. It has the additional benefit of promoting weight loss and it also fits the bill in a lot of other ways. It's a fixed-dose product, meaning that the patient does not have to measure blood sugars and do some kind of calculation and then take the shot. They basically dial out a dose, shoot, and they're done for the day. From an administration standpoint, it's pretty simple. The drug is safe; it's effective; the data is really good.

Yet during the clinical process, they discovered that there was some formation of what they call C-cells, which could lead to thyroid cancer. Now I'll be upfront. I'm not an expert on thyroid cancer, but I've talked to a lot of guys. There are two different kinds of thyroid cancer: One is serious, one isn't. What happened was the FDA had a panel meeting on this drug. Basically when the drug was approved, it came out with a black box, which is a pretty serious warning about the possible risk of thyroid cancer. Now to me what makes this a little bit ludicrous is that all the noted experts in the field basically use this one chart, which shows on one axis over the last — I think it's 25 years — the increasing rate of thyroid cancer. Yet on the other axis, the mortality rate of thyroid cancer has almost flat lined over that same time frame. What this means is that thyroid cancer is very slowly growing, it's not life threatening, and it is detectable. That's one reason why you're seeing this increase in the diagnosis but yet treatment is pretty simple, and that's why it's not a very "life-threatening" situation. The FDA is

Highlights

David A. Kliff discusses major trends in the diabetes health services segment, explaining the various ways in which today's economy affects the drug approval process. He offers an in-depth analysis of current FDA issues as well as his own critiques of current health care delivery in the U.S. Mr. Kliff also highlights several pharmaceutical and medical device companies that are successfully capitalizing on the business aspect of the world's diabetes epidemic.

Companies include: Novo Nordisk A/S (NVO); Amylin Pharmaceuticals (AMLN); Eli Lilly & Co. (LLY); Alkermes (ALKS); Sanofi-Aventis (SNY); DexCom (DXCM); Insulet Corporation (PODD); Merck & Co. (MRK); Bristol-Myers Squibb Company (BMY); AstraZeneca PLC (AZN); Novartis AG (NVS); Kraft Foods (KFT); Unilever plc (UL); CVS Caremark Corporation (CVS); Walgreen Co. (WAG); Rite Aid Corp. (RAD) and Safeway (SWY).

thinking, "Should there be some kind of label about this? Should it be a black box warning?" A lot of people, myself included, believe it's overly conservative. That's one example.

"The biggest trend that's happening right now really centers on the FDA with the Avandia controversy. I don't want to say this has turned the FDA on its head — that's probably an overstatement — but it has changed the dynamic to such an extent where it almost seems like the FDA is looking for reasons not to approve new drugs or new devices."

Another example is that because the FDA has been preoccupied with Avandia in deciding what to do there — this is a drug that's been under siege now for over two years — clearly sales have fallen into the abyss. But the FDA wouldn't wait to do things; they want to get their last pound of flesh there, and so they hold the panel meeting. While they're doing all this stuff, all these other diabetes drugs and devices have been basically put on hold. Bydureon, which is from **Amylin Pharmaceuticals** (AMLN), **Eli Lilly** (LLY) and **Alkermes** (ALKS), is a once weekly GLP 1. They basically gave it an approval letter but then said, "We have to push you off until October and it has nothing to do with the drug; the FDA isn't ready because they're still dealing with other garbage from Avandia." The same is true with devices. The FDA, it seems to me like the agency has lost perspective and balance. I think that this is not uncommon in Washington; we go through these cycles. We went through a cycle with the FDA where people were saying that it's taking too long to get drugs to market; the approval process is too onerous. Everybody was coming down on that.

Then we went through a period where all of a sudden, you're hearing stuff like, "They are too close to the pharmaceutical industry, there is not enough study done." We've gone from one extreme to the other. Now as the pendulum starts to swing back, we've got to find somewhere in the middle. Unfortunately, that does not happen really well in Washington, D.C.; we tend to move from one extreme to another. The truly sad part of this entire situation is that you have a disease state that continues to grow at epidemic rates and people are needlessly suffering because basically you've got a bunch of people who just can't seem to hit water if they fell out of an ocean liner. That's the biggest trend that I see.

To me, when I look at this, it's a question of risk-reward, meaning that nobody wants a drug to contribute to a problem. No person in their right mind would even say that. But there's got to be some balance brought to the situation, meaning what's worse: Diabetes is a serious life-threatening disease that is not controlled; two-thirds of all patients are not under control. This has not only devastating health care consequences but economic consequences as well.

I would reason that these people need more tools, more weapons to fight this, and not less weapons. It's like war. Nobody likes war because people die. Rule number one in war is good men and women are going to die. Rule number two is you cannot change rule number one. That's the nature of war. Nobody likes it, but that's the reality. Drugs are the same way. There is no such thing as an adverse event-free drug. Aspirin has adverse events. It's a question of degrees and numbers. Part of the problem is that we've become so conservative. Are we going to pull the drug off the market because one person dies yet a million people are taking it? That doesn't seem equitable to me.

I think that's part of the problem here — we've lost some perspective. The use of meta-analysis has devastated things. We were supposed to be basing this on science. There's an old saying, "Liars figure and figures lie." Meta-analysis is just like that because you're getting into a loony world, when at the last panel meeting for Avandia, there were like four statisticians on the panel meeting arguing over which number should be counted and which study was most accurate. It's not like a football game, where at the end of the game the person with more points wins. This is data that's open to live interpretation. I view meta-analysis like abstract art. You walk into an art gallery and one person looks at that picture and says, "Oh, my god, its worth a million dollars," and the guy standing right next to him says, "It's a piece of junk, I wouldn't pay two cents for that." Same picture, yet two different perspectives. That's what meta-analysis is like.

1-Year Daily Chart of Novo Nordisk

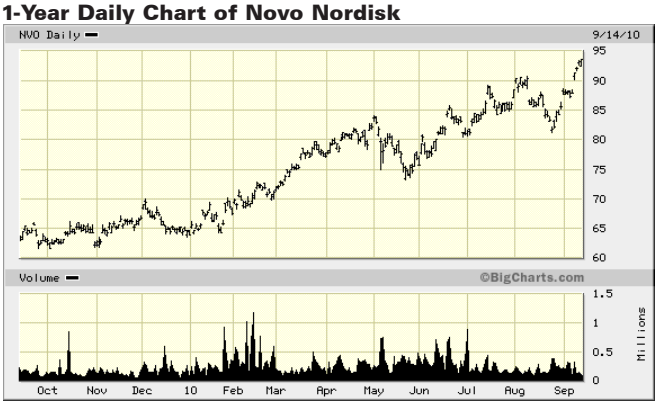

Chart provided by www.BigCharts.com

The fact is physicians and patients want simple answers to complex questions, and that's not going to happen. A patient seen in the doctor's office, when he asks his doctor or her doctor, "Is my medication safe?" doesn't want an answer, "Maybe." They want a simple "Yes" or a simple "No." Today you can't do that. That's contributed to this whole problem. I don't want to say it has become ludicrous, but it's almost ludicrous. There was a report out yesterday that it turns out, and the study was published in *Circulation*, which is a respected cardiology journal, that said Actos is just as dangerous as Avandia. This is a drug that has about $4 billion in sales. Now already physicians have thrown Avandia out of the medicine cabinet. Now they're going to throw Actos out of the medicine cabinet. What's last?

Seriously, we're getting to a point where it seems like no matter what drug there is, there's a problem. Insulin, which has been around for — I don't know how many — for years has side effects.

Metformin, it's one of the most widely prescribed generics, it has side effects. There is no way to get around it. I think what most people would like is quality information so they can make an informed decision. But what's happening today is that because of the media, the way information is disseminated, there is 24-hour news cycles, banner headlines and all that kind of stuff; there is no perspective brought to a situation. There is a lot of confusion. I don't blame people. If I'm confused about what's the easiest way to do it, don't take it and then I know that I'm okay. They may not realize that the consequences for not taking it are actually worse. It's made for a very difficult time, not just not diabetes, this is a lot of chronic disease states, but diabetes in particular because diabetes is growing at epidemic rates and there is no end in sight.

"The fact is physicians and patients want simple answers to complex questions, and that's not going to happen. A patient seen in a doctor's office, when he asks his doctor or her doctor, 'Is my medication safe?' doesn't want an answer, 'Maybe.' They want a simple 'Yes' or a simple 'No.' Today you can't do that."

TWST: The growing epidemic brings me to question the efficacy of health care delivery. How do you see that?

Mr. Kliff: Nothing in this country is going to change until physicians are paid for achieving better outcomes. All this talk about health care reform and all this talk about preventive medicine and educating patients, that's wonderful. But physicians are not paid to prevent diseases or achieve better outcomes; physicians are paid to treat people. Until that changes, everybody is fooling themselves when it comes to health care. Because the reality is there are so many things broken with the system. Physicians, if they are honest with you, will tell you, "Hey, we have to warehouse patients just to keep our lights on." And that's the truth. Physicians aren't stupid; they understand. They want better, they want their patients to be better educated; they know that therapy compliance or non-therapy compliance is one of the major reasons why we're not seeing better outcomes. But the reality is that they don't have the time nor are they reimbursed to spend time with the patients, telling them what they need to do and why they need to do it.

Ask anybody who's been to a physician — it's all the same thing. It's a weird situation in this country we live in now, where people are paying extra to have guaranteed face time with their physician. Who would have thought that people would pay for a service that once was considered part of physician's job? How crazy is this? But that is what we've come to. For the average American on the street, they don't get that. Believe me, if doctors were compensated, they've got a bonus for every patient they got to an A1C below 7, my god, I'll make you a bet they would do their damn best to get him there. But that's not how they're paid. We've got to stop this foolishness and say medicine is a business. These guys are businessmen. I understand that there are people out there that believe physicians should be altruistic and give their time; that isn't the real world. It's wonderful when they do those kind of things, but the reality is they've got families just like you and I. They've bills to pay and god bless them, they want to make a profit. This is America. I told people all along while I applaud trying to get everybody in this country covered, coverage doesn't guarantee anything. All it means is that you're covered, it doesn't mean you're getting quality care; it just means whatever care you're getting is paid for. I think fundamentally the bottom line is until we change the paradigm, everybody is kidding themselves; it's not going to change. You pay people to get better outcomes, believe me, it's going to happen. That's not what's going on right now.

TWST: What about the companies who are working on new products?

Mr. Kliff: I think the trend you're going to see in diabetes, and there is no question about this, it's connectivity. What I mean by that is where all the devices and drugs talk to each other. Here's an example: **Sanofi-Aventis** (SNY), they make LANTUS, it's the world's number one selling insulin. They also have a short-acting insulin called Apidra. They are expanding into devices, whether that be blood glucose monitors, insulin pumps, insulin pens, they also have a GLP-1 under development. They've really made an effort to become a dominant player in diabetes. In fact, their stated goal, they've stated it publicly a million times, is they want to take on **Novo Nordisk** for the leadership role in diabetes on a global basis. Now **Sanofi's** plan basically is to deal with diabetic patients as patients for life. They want to sell them everything they can in that life, everything from the drugs that they use for their disease to the devices they use to help manage their disease. They want to connect all this stuff and be almost like a health coach for this patient. I wrote many years ago that at some point in the future, we're going to see where a patient is going to walk into a physician's office and they are going to be prescribed a diabetes management system rather than individual pieces of the system, and that's where we're heading. The system is going to be augmented by technology, whether it's cellular technology, Internet technology, whatever. That's going to happen.

1-Year Daily Chart of Sanofi-Aventis

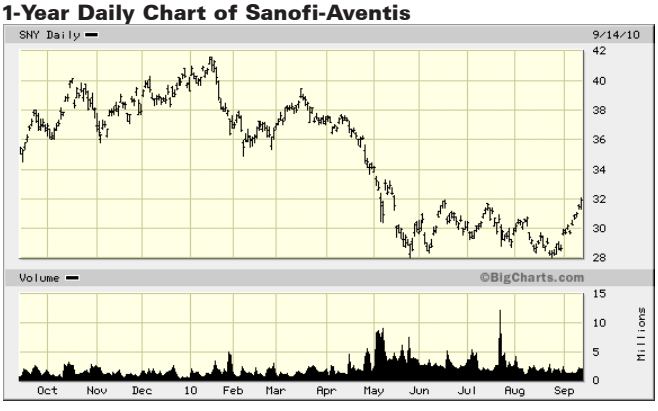

Chart provided by www.BigCharts.com

When you look at this big broad spectrum here — and **Sanofi** is moving in that direction because eventually you're going to walk into that doctor's office, and he's going to say, "Hey, every-

thing you need is in this nice little box" — that's kind of where we're going. We're not there yet, but we are moving in that direction.

"Nothing in this country is going to change until physicians are paid for achieving better outcomes. Physicians are not paid to prevent diseases or achieve better outcomes; physicians are paid to treat people. Until that changes, everybody is fooling themselves when it comes to health care."

Diabetes is a huge market. I think the latest numbers are 26 million patients in the United States; 20 million are diagnosed, one in three children born today are going to develop diabetes. The WHO says that the number of cases of diabetes worldwide is going to double by 2025. The numbers are incredible. Everybody wants in for the business. Then you add in all the obese people. One of the things that also becomes apparent is that because the market has become so big, you really have to have some scale to make it work. That's why you're seeing companies over the last five, 10 years, we've gone from six or seven major blood glucose monitoring companies down to four. Out of that four, we're probably going to see even further consolidation. Scale is very important in this business. The same thing is true with drugs. It's so expensive to get a drug all the way to the market. It's not unusual that you're now starting to see bigger players dominating diabetes even more so than it was in the past. It doesn't mean there isn't room for the little guy, it just means that the road is a little bit tougher. I see the landscape kind of changing. I see some companies, **Sanofi**, **Novo Nordisk**, are viewing this disease on a global basis and are not just focused on the Americas or Europe. They're starting to realize, "Hey, India has a problem, China has a problem." The problem has always been how do you get what you're selling to the patients and is there a middle class there to support it? But it's coming. We are not there yet, but it's coming.

TWST: We've talked about diabetes-related drugs and the situation there. What about new technologies and tools, like the closed-loop insulin delivery systems?

Mr. Kliff: I've written a lot about artificial pancreas. Here is my problem with it: Who is going to pay for it? Nobody is bothered to look at the regulatory path. They don't think of even the basic elements of a closed-loop insulin delivery system, an insulin pump combined with a continuous blood glucose monitor. All of these things have to work all the time because here is a simple fact: Let's say hypothetically that something goes wrong. If you deliver too much insulin to a patient, you can kill them. I'm not saying that it can't be done. I know it can be done. But in today's environment, where these devices are already pretty expensive, it's not economical. Additionally, how many people is this going to really apply to? I'm not necessarily against the closed-loop insulin delivery system, I just think that the path to get from point A to point B is nowhere near as easy as these people think it is.

I think quite honestly it does more harm to the overall research in diabetes than good because let's be honest about it: There are only about a million patients that system would even apply to. The reality is unfortunately there is a huge bias in this world when it comes to non-insulin-using patients, like somehow they're not worthy of diabetes or diabetes research dollars. But meanwhile they make up the majority of the market. We've got a lot of smart people out there. Question is, is it worth the effort?

I relate this to the efforts to develop a non-invasive blood glucose monitor. I've been covering diabetes for 15 years and still people think this thing can be achieved. What I said from the very beginning is I don't care if you hand a completely non-invasive device to a patient, if the patient doesn't understand what those test results mean and how to use that information for their personal benefit, it just doesn't matter. With a closed-loop system, you're talking about a extremely complex device that must work all the time. These are machines; they break, they malfunction. I wear an insulin pump. I wear a continuous glucose monitor. I love them, but they do make mistakes. It happens. I don't want to be taking on a loop. I don't want a machine in control of my life and a lot of doctors feel the same way.

1-Year Daily Chart of DexCom

Chart provided by www.BigCharts.com

TWST: What about the investing side of diabetes-related stocks? What companies have you been looking at in the investment world?

Mr. Kliff: One of my favorites is **Amylin Pharmaceuticals**. They are partnered with **Lilly** and **Alkermes** on BYDUREON, which is a once-weekly GLP-1; one of my favorites. I like the company **DexCom** (DXCM). They make continuous glucose monitors. I think they make the best system out there. More importantly, I think they are an extremely well-run company that will eventually be bought by somebody else. They'll never survive as a stand-alone company. They're doing very well. The reality in the device world is typically once you've established yourself, a bigger player comes along and buys you, and that's what I think is going to happen with **DexCom**.

I've also been following a company called **Insulet** (PODD) for several years. They make a wireless insulin pump. I think eventually somebody will acquire them as well. Those are a couple that I follow very closely. I watch all the big guys, obviously

Merck (MRK), **Lilly**, **Sanofi-Aventis**, **Novo Nordisk**, **GlaxoSmithKline** (GSK), **Bristol-Myers Squibb** (BMY), **AstraZeneca** (AZN), **Novartis** (NVS). I follow all of these companies. I think that for the big guys, it's a little bit different because with the exception perhaps of **Novo Nordisk** and **Sanofi-Aventis** — and really more for **Novo** than it is for **Sanofi**, although **Sanofi** probably will get there — diabetes is cornerstone of what they're doing. Somebody like **Lilly**, that used to be a major player in diabetes, I don't want to say diabetes is an afterthought for them, but because of series of events, diabetes is no longer the cornerstone of **Lilly**. It's a part of **Lilly**, but it's not what it was. When I look out there, and I'm looking at investment opportunities, I tend to look for companies who are anticipating trends correctly.

"I like the company DexCom. They make continuous glucose monitors. I think they make the best system out there. More importantly, I think they are an extremely well-run company that will eventually be bought by somebody else. They're doing very well. The reality in the device world is typically once you've established yourself, a bigger player comes along and buys you, and that's what I think is going to happen with DexCom."

That's why I'm such a strong believer in **Sanofi-Aventis**, because from my research with the company, my interviews with them, looking at what they're doing, I think that **Sanofi** brings with them kind of a new fresh perspective, and they understand the real world. There are a lot of companies out there that live in an ivory tower and don't really understand what a patient goes through ever day in their lives. I'm not talking a patient like me; I'm a terrible example. I'm a boy with my toys. I have all the latest tools plus I have access to the greatest minds in the world. If I have a question, not only do I have a great endocrinologist, but I can call up the world's greatest researchers because I know them and I get access. Most people aren't like that. Most people don't have what I have. I've always said, "Diabetes is a job." You have no days off, and if you want to be good at your job, you have to work at it every day. This is very apparent to me in the last few major diabetes shows, a lot of companies have kind of lost their way. They forgot that there's a patient at the end of the line.

Part of this has to do with the maturity of the market. Maybe 10 years ago, diabetes was just emerging on the scene as a disease state where everybody wanted to be in. Now the market has matured; bigger companies are in the market, and they understand the dynamic. I think we're starting to see less revolutionary changes and more of what I call baby-step incremental changes. That's the natural evolution of a market. It gets to be problematic for me, because like for example, I see a lot of drugs where I call them "me-too" drugs where if you look at the data, they do the same thing as drugs that are already on the market, it's just a different way. I'm a believer that we are moving towards a system where not only will the FDA look at drugs from a safety and efficacy standpoint, but I think eventually they are going to say is it better financially than what's already on the market. If it merely does the same thing in the same way and there was no compelling benefit, that's the key.

For example, if you look at Januvia, which is from **Merck**, it has been on the market for a few years. It's a leading oral antidiabetic. The drug, its sales were in the billions. But Januvia is from a class of drug called DPP-4 inhibitors. There's another drug on the market from **Bristol-Myer** and **AstraZeneca** called Onglyza. If you look at the data for the two drugs side by side, they are mirror images of each other, and there's no compelling benefit to use one of the same dosing schedule, same everything. I think in the future, you're not going to see a lot of that anymore. I think you're going to see where the FDA would say, "Hey, I have a once weekly version of this rather than once daily." That's a compelling benefit. It's like those Sally Field commercials of Boniva. I think she takes a dose once monthly, it's a lot better than taking pills every day. I think we're moving in that direction, where the British have a system called NICE. We're going to move in that direction, so they look at the cost benefit relationship of a drug. I think we went from a time where if the drug lowered A1c, everybody said, "It's great, let's approve it." Now we've got all these other things added on, and I think that the next logical thing that they're going to add on is, "Hey, is it cost effective? Is it really better than what's already on the market?" The reality that I see here going forward into the future is that people need to realize that when they're making their investments, especially in what I call the developmental area, whether its drugs or devices, the landscape does not favor those kind of companies right now. The path is so difficult now. Drug development has always been a risky business, but it's become even greater so because of what's going on with the FDA.

"Maybe 10 years ago, diabetes was just emerging on the scene as a disease state where everybody wanted to be in. Now the market has matured. I think we're starting to see less revolutionary changes and more of what I call baby-step incremental changes. That's the natural evolution of a market."

The same thing with medical devices — there isn't anything out there quite honestly that you look and say, "Wow, that's cool, that's great." There's nothing out there that just grabs you and says, "Boy, this is really going to a make a difference." I don't want to say those days are over but for the time being, this is really in some respects unfortunate. It has become a battle of market share rather than innovation. I'm not saying that's necessarily bad, that's just a fact of life; the market has matured. At one time there must have been — I don't know how many — 20 computer manufacturers, and now we're down to three or four. It's natural evolu-

tion of the market. Some people just don't want to accept that, but that happens to be the reality.

TWST: You have talked about companies that are doing well by providing services to diabetics, like the pharmacies and food companies. Do you see any new developments in those areas?

Mr. Kliff: There's no question that all the major food companies, **Kraft** (KFT) — what's the other? — **Unilever** (UL), all of these companies have recognized that patients are actively seeking out diabetic-friendly products. They are putting more emphasis on it, plus as everybody knows, everybody is more health conscious these days, more weight conscious. That dovetails very nicely. I think you're seeing a shift in the retail community, both from retail pharmacies, like **CVS** (CVS), **Walgreens** (WAG) and **Rite Aid** (RAD), and grocery chains, like **Safeway** (SWY), where they're looking for new ways to attract patients with diabetes, but they're very valuable. We're the golden child of the pharmacy. We always need stock, whether it's drugs, refills and test strips, whatever. The average diabetic patient is worth $4,500 a year to a pharmacy. You don't get too much of that. There is all this talk about helping the patients, but there is this huge disconnect between all the players because everybody talks about it but nobody wants to pay for it. The insurer has got one agenda, the retailer has got another agenda, the HMO has got another agenda, and yet all these people, they talk a really good game but nobody really wants to go out there and say, "You know what, we're going to take the bull by the horns and do this." They're all looking for ways — "We don't want to pay for this." So we want to dump the class and somebody else would be the beneficiary of the result because quite honestly, nobody really has figured out how the total health services model works. What's happening is everybody is kind of waiting for what I was talking about earlier. I think everybody sees that at some point, better outcomes will be compensated, and they want to be part of that.

Right now everybody's kind of struggling with how to do that. What patients struggle with even worse is that, caught in the middle of all of this is the patient who really today has some of the best tools and some of the best devices at their disposal. But the two mean they're going to be used. When I look at all of this stuff that's going on, there's a lot of cool stuff but nobody has really figured out how to connect all the dots, and nobody quite honestly has these different sections that say they should be working together. They really aren't working together because everybody wants to get the money at the end of the rainbow, but nobody wants to do the heavy lifting to get there. I think everybody knows what's needed, but nobody wants to cooperate and give a little bit up to get something greater.

Right now we're at the stage where they want it all and they're not going to get it all, and it's only going to make things worse. I know some pharmacy retailers in particular I've looked into who are trying to help diabetic patients achieve better outcomes. They want to be paid for their efforts. They don't seem to understand that if you do this, though they will be paid, it'll just be in a different way. They're not going to be paid by a third party; they'll be paid by this consumer being more loyal to their pharmacy. They're in the store more frequently, buying more things; they're staying more compliant on their therapy. I think some of these retailers are beginning to wake up and say, "Hey, we're not going to be paid by insurance companies to educate patients." They want to do it. They don't want to pay us. Quite honestly, educating and helping a diabetic patient, it's not a one-shot deal. It has to be done on a regular basis; it's a chronic disease. The reality is it's just expensive. You have to bridge all of these gaps to get from point A to point B, and I think that any pharmacy chain that did this would be highly rewarded. I just think that they're doing it in the wrong way. I think that they're putting sales in front of education, where education could drive sales. They just don't see it that way.

TWST: What else would you like to add that we didn't touch on in the interview?

Mr. Kliff: I think what I would add to everybody is kind of a word of caution. I think all I want to add is very simple: I think people need to move cautiously here. We've seen a lot of extravagant claims being made, and I think before people get ahead of themselves, they need to understand the road map to success. And whether it's a drug or device, that road map right now is going through the FDA. The FDA, in several respects, I feel very sorry for the agency because of the pressure they're under. But I do understand why they're doing and what they're doing. It is important for investors to understand that that path to success has just gotten more difficult, not less difficult. I look at things now; In the past, I maybe didn't look so hard — not because I wasn't concerned, just that I knew that the path was easier. But now you really have to drill it down, you have to really do your homework because, I got to tell you, the FDA sure is, and they're not going to make it easy on anybody.

TWST: Thank you. (PS)

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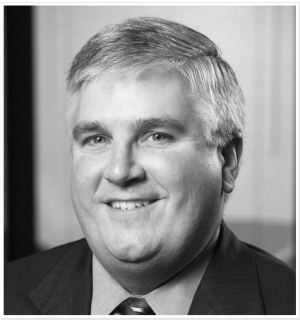
Haemonetics Corp. (HAE)



BRIAN CONCANNON joined Haemonetics Corp. in 2003 as President, Patient Division, and was promoted to President, Global Markets, in 2006. In 2007 Mr. Concannon was promoted to Chief Operating Officer. In April 2009 he was promoted to President and CEO and elected to the Haemonetics board of directors. Immediately prior to joining the company, Mr. Concannon was President, Northeast Region, for Cardinal Health's medical products and services, where he was employed since 1998. From 1985 to 1998 he was employed by American Hospital Supply Corp., Baxter Healthcare Corp. and Allegiance Healthcare in a series of sales and operations management positions of increasing responsibility.

SECTOR — HEALTH SERVICES

(ALF604) TWST: Would you start with a brief historical sketch of the company and a picture of the things you're doing at the present time?

Mr. Concannon: Haemonetics is a Massachusetts company founded in 1971 by an MIT-trained engineer by the name of Jack Latham, who was retiring from a long career with Arthur D. Little. Jack invented a single-use plastic chamber to separate a volunteer blood donor's whole blood into its parts — red cells, platelets and plasma — that ended up revolutionizing transfusion medicine by improving the safety and availability of blood components for patients who depend on blood transfusions. For example, millions of cancer patients who require platelet transfusions during their chemotherapy received better clinical care because of Jack's invention. The same technology first applied to separate platelets from donor blood was later used to collect and clean, and essentially "recycle" surgical patient's blood during and after surgery. As you might imagine, providing a patient back with their own blood versus receiving a blood transfusion from a donor is the very best and safest blood that any patient can receive.

TWST: What's happening these days?

Mr. Concannon: We've migrated beyond being just a medical device company. Since Jack's original inventions, we expanded into a number of different areas. In the plasma field today, Haemonetics' devices and disposables are used in the collection of roughly 70% of all plasma in developed countries worldwide that is used to manufacture plasma-derived biopharmaceuticals. In this market, our customers are the companies that are making and selling IVIG, albumin and Factor VIII, so we provide devices they use to collect the plasma used for the raw material they need to produce the drugs. Our devices are also used to collect platelets for patients in surgery or cancer patients who need therapeutic transfusions during their treatments. Then more recently, we developed a technology to double the volume of red cells safely collected from a volunteer blood donor, through the same "apheresis," or separation technology we use to collect platelets and plasma. This technology makes more efficient use of blood donors whose "gift of life" is critical to the practice of medicine today. So that's on the collection side.

On the hospital side, we have devices called the Cell Saver® to recycle a patient's blood, used primarily in cardiovascular surgery. We've migrated into orthopedic surgery, where we developed a smaller device called the OrthoPAT. It handles lower blood volumes over a longer period of time, both interoperatively and post-operatively, because there is a lot of bleeding now that occurs post-operatively, particularly in orthopedic surgery, where again, a patient's blood is salvaged, red cells are separated, washed and provided back to the patient. Again it's a much more beneficial way of being able to treat a patient clinically. So that's the way we've grown over time. In each blood donation event or patient blood recycling event, our technology is comprised of a device and a single-use plastic blood collection chamber we call a disposable. Almost 80% of our revenues come from sale of the single-use disposables. This is the so-called razor blade of our razor/razor blade business model.

About four years ago, we saw the opportunity to go beyond just simply the medical device focus into what we call blood management. This was born out of an acquisition in 2002 of a Canadian company called 5D. 5D developed a software product that managed the collection process in plasma centers. It is really through taking this concept and expanding it first in the plasma environment, using software and our devices and disposables, as well as services to understand the customers' operations and solve their problems, that we transformed from a company that provided device and disposables to one that provided solutions that address our customers' blood management needs. We went from about 40% market share four years ago in the plasma collection area to over 70% today, and it was really by broadening our approach to solving a customer's problems. We're now taking that same thought process, that same philosophy, that same vision of blood management to the hospital and blood center collection environment and helping those customers to understand what their critical pain points are and how we can work with them to solve those issues and find more economically and clinically beneficial ways of managing in their environment.

TWST: Tell me about your background and maybe

briefly some of the key members of the team.

Mr. Concannon: My own background — I graduated from West Point in 1979 and after almost six years of service, I left the military and joined a company called American Hospital Supply — kind of an ironic story. I grew up here in the Boston area, in fact in the town next door to where Haemonetics is headquartered, and I started with American Hospital Supply in its New York office, actually located in New Jersey. American Hospital Supply owned a company up here south of Boston, and I felt, boy, wouldn't it be great if I keep my nose clean and do a good job, maybe I'll get transferred up to Boston closer to home working at this company. In 1985 American Hospital Supply was acquired by Baxter Corp. and as a part of that transaction, the U.S. Justice Department required Baxter to spin off that small company located up here in Boston because it competed with a larger division of Baxter. That company was Haemonetics, so my dream got dashed in 1985. Then I find myself here all these years later. So I grew up in American Hospital Supply, and Baxter was with them for about 10 years. And then Baxter spun off what was essentially the American Hospital Supply acquisition, creating a company called Allegiance.

I remained with Allegiance Healthcare and became President of one of its businesses. Allegiance was acquired 27 months later by Cardinal Health, after the spinoff from Baxter. I remained with Cardinal Health for about five years as one of the Presidents of its businesses and then left Cardinal Health in 2003 to come here to Haemonetics under Brad Nutter's leadership. Brad had just joined as our CEO, having come out of retirement after a career at American Hospital Supply, Baxter, Syncor and Gambro. We basically split the company into the patient and donor divisions, and I came here to head up the patient division. Eventually I moved to President of Global Markets and then to the Chief Operating Officer, with responsibility of restructuring the business internationally. I completed that and then was selected by the board in October of 2008 to replace Brad effective April 2009 as the President and CEO. So that's a brief background for me.

One of the things that Brad did so well was really focus on building a team here, and I feel we've strengthened it even a little bit more since he's moved on, as we brought in some new key players. Heading up our North American business is a gentleman by the name of Mike Kelly. Mike is new to our organization and has been here two months now. Mike joined us from CareFusion, and Mike has responsibility for our North American business and our worldwide plasma business. Mikael Gordon, who we recruited from GE Medical, is Mike's counterpart who heads up all of our international businesses, with the presidents of Japan and Asia Pacific reporting to Mikael, as well as our European direct and our European distribution businesses. Pete Allen is our Chief Marketing Officer. Pete joined the company with me back in 2003 and was the President of our donor business at that time, and since moved into the Chief Marketing Officer role and has been there for a number of years now. Pete has primary responsibility to communicate our blood management vision and manage how we take our full portfolio of products and services to market.

We've got Chris Lindop, who is our Chief Financial Officer. Chris joined the company about four years ago now from Inverness. In a previous life, Chris had been the audit engagement partner for Haemonetics, so Haemonetics was well known to Chris, and Chris was well known to Haemonetics. Chris not only brought strong technical knowledge from a finance standpoint, but Chris really brought strong expertise and experience in business development as well. Since Chris has joined us, we have made about 10 acquisitions during that time frame, which is the real build out of our blood management vision — most of that in the software space as we built an IT platform, but also some blood management technologies with the same kind of razor blade model that we have for our legacy business.

"More recently, we developed a technology to double the volume of red cells safely collected from a volunteer blood donor, through the same "apheresis," or separation, technology we use to collect platelets and plasma."

Jonathan White is our Vice President of R&D. He has responsibility globally for our R&D efforts. He joined the company a little over 18 months ago now from Pfizer and has been a real solid addition to the team, and brought a strong technical and IT focus across all of our businesses. This becomes important because his global reach has not only the responsibility of our devices and disposables, but includes making sure now, given our blood management vision, that these devices all talk with the softwares that we've acquired as well. So he's got a huge responsibility in doing that. Joe Forish is our Vice President of Human Resources, been here over five years now and brought some real focus from a talent development and succession-planning standpoint. Phil Brancazio joined us a little over a year ago from Watson Pharmaceuticals as our Vice President of Global Manufacturing and Delivery. His experience dates from the early days of Bristol-Myers Squibb, and he brings a real solid manufacturing background to the team.

TWST: You mentioned you have 70% market share. What's the competitive landscape like and what do you see as some of your competitive advantages?

Mr. Concannon: What I think you have to do is break it down into the different pieces. In the plasma arena, where we have 70% market share, the key competition there is Fenwal. Fenwal is the spinoff from Baxter a number of years ago, so that's our primary competition there. In the platelet arena, we compete with Fenwal and Caridian, the spinoff from Gambro BCT. Both Fenwal and Caridian are now in the hands of private equity owners. In the double red cell business, there are two players in that space, us and Fenwal, and we have market share leadership there as well.

When I shift over into the hospital side of the business, where I look at cardiovascular cell salvage, there are three competitors in that space. The combination of Sorin/Dideco/Cobe under the Sorin brand, which is an Italian cardiovascular company, has a cell salvage device as an extension of its cardiovascular services. Medtronic, the U.S.-based company much like Sorin, has a cell salvage device as an

extension of its cardiovascular services. Fresenius built a cell salvage device and has very small share based off of its renal technology. So those are the competitors in that space.

As it relates to orthopedic cell salvage, we're the only company that has a device specifically for orthopedics and specifically that can be used both interoperatively and post-operatively traveling with the patient. Now many of the cardiovascular cell salvage devices can be used in orthopedic surgeries depending upon blood volumes, but it becomes more difficult for them to be used post-operatively. So that's the landscape there.

In the area of software, we have made a number of different acquisitions here, where we have products that compete across a wide swathe of the industry. In the plasma industry, there is us and a company called MAK, which is developing a product as we speak. It's a French company. In the blood center arena, there is Haemonetics and then MAK, and Mediware is another U.S.-based company that competes in that space. A lot of small software companies compete in that space in a number of different areas. We've got the largest breadth of products across all of those disciplines. The value of what we do is the combination of our devices and disposables, so our existing technologies can speak to and through our software platforms and our services, and in this way, we're able to really understand a customer's pain points and solve those problems. We're the only company as well that is both in the demand side of blood transfusion, which is hospitals, as well as the supply side of blood transfusion, which is the collection environment.

TWST: The recent investor presentation said the collapse of the global economy gave some challenges in FY 2010, including fewer surgeries and capital budget constraints. How did the company deal with those challenges?

Mr. Concannon: You're chasing a shrinking market for a period of time, and it really would need to be broken down into each of its different markets. First of all is truly understanding the market. Is it something that's being affected by the economy or is it something that's being affected by surgical techniques? Surgical techniques are continuing to improve, where you're seeing less and less bloodshed; however, you're seeing more and more surgeries as the population ages and the demand for blood increases. We saw a small dip in that recently because of the economy, mostly in the number of elective procedures, primarily orthopedic elective surgeries. So it's really understanding what's taking place there and then how do we address that. It's really driving in the developed world our blood management solutions because these are ways we can affect a hospital's ability to manage blood both in terms of economic impact as well as the clinical impact of using blood. So it's really something that's much more powerful as you partner with your customers to understand what they're doing and how they're doing it.

TWST: What does health care reform mean for the company and how are you taking advantage of the new rules in order to deal with any challenges?

Mr. Concannon: If you think about just what I said there, I think any company that can work with their customers to help them improve clinical outcomes, improve their economics and improve quality is going to benefit. If you can do any one of those things in this new world of health care reform, you're going to be in a good position. And we can do all three. So here we have arguably 30 million to 40 million more Americans with access to health insurance, and the health care system that is going to need to find a way to afford to do that and do that more effectively, more efficiently and in a way which delivers better clinical outcomes. I think we're very well positioned with our blood management solutions to help our customers do that and get to that point rapidly. At the end of Q1, we had 90 accounts engaged in what we call "full blood management," and those accounts with us are up dramatically in their use of our blood collection technologies. And these are accounts that vote with their dollars.

"We're the only company as well that is both in the demand side of blood transfusion, which is hospitals, as well as the supply side of blood transfusion, which is the collection environment."

We launched a new product at the end of last fiscal year called Impact Online, and it automates a hospital's ability to get in, and mine and manage its own data on its blood transfusion practices and events. We're able to get that data for them through a Web-based portal and then provide them access to that data. This is data that comes from multiple sources in a hospital and put into a meaningful usable format, so that they can look at blood, how it's being utilized, and the impact both economically and clinically on their operation and on their patients. In a nutshell, the beauty of that is not only is it beneficial clinically and economically to the hospital, but it really is our report card. It shows that we are doing what we said we would do. Is this bringing the value we said it would bring? So it's great for them and great for us. We like being in that place.

TWST: Finally, from that presentation, you forecasted that revenue this year will rise 9% to 12%, operating income up 11% to 14% and earnings per share of $3.15 to $3.25. Would you give us a sense of whether that forecast is holding up? Also what are the keys to reaching those numbers?

Mr. Concannon: We're in the middle of a quarter now; I will simply say that's what we reiterated at the end of first quarter. We came out of our first quarter with confidence, although some have argued that our numbers showed weakness, and they did, but primarily in the area of plasma. We provide annual guidance, but we had, at the end of last year, provided our analysts and shareholders with some visibility into the quarterly expectations for plasma, because in fiscal year 2010, we saw plasma slow down and decelerate pretty rapidly. We saw 26% growth in Q1, 19% growth in Q2, 10% growth in Q3 and basically flat in Q4. So you saw something that was decelerating as we expected finishing with 15% growth for the year, and that was driven by supply coming in line with demand. So our plasma customers are burning off this inventory glut. So that's where I think most people have had their questions. And is this market going to rebound? Some of the most recent PPTA data continues to reinforce the improving stability in this marketplace.

TWST: You mentioned you've made several acquisitions. What's your strategy going forward on that front?

Mr. Concannon: We'll continue to use cash as we have in the past, and we really generate a fair amount of cash. Our target is to generate north of $70 million free cash this year, and our priorities for this cash are first, for smaller bolt-on acquisitions that continue to support our blood management vision, and secondly, the buyback of our stock. When you look at the acquisitions that we target, our focus has been primarily building on our information technology foundation. And I think for the most part, we substantially completed that. There may be some other smaller opportunities there, but we'll now look to continue to bolt-on products that help our customers manage blood differently, not unlike the Haemoscope acquisition we made a couple of years ago with thromboelastograph, a great example of a device that is really being embraced from a blood management perspective today. It is one of our fastest-growing product lines today.

"We'll continue to use cash as we have in the past, and we really generate a fair amount of cash. Our target is to generate north of $70 million free cash this year, and our priorities for this cash are first, for smaller bolt-on acquisitions that continue to support our blood management vision, and secondly, the buyback of our stock."

TWST: You provided a couple of highlights to your strategy to leverage core business to improve profitability and to expand the business by leveraging core competency. Would you briefly explain the core of those two plans?

Mr. Concannon: We have one vision, two strategies. The first one, leverage the business to improve profitability. The second is to leverage our core competencies to expand the business. These strategies haven't changed in the last four years. In fact, these strategies have been with us for longer than that. We like to say that we really are trying to narrow our focus and be not only good, but great at what we do. If you go back seven years, we had a margin of about 46%. Our margin last year was north of 52%. We expect to grow margins this year in excess of 100 basis points. We believe that there is still profitability to be gained in this business and how we leverage the business. We have a philosophy that for every incremental gross margin dollar we generate, we pump $0.65 of that back into the business, and $0.35 drops to the bottom line for our shareholders. So we continue to invest strategically in the business in an important way, and that's our focus. During that same time, not only did we expand our gross margins by about 700 basis points, but we went and doubled our operating margins. So we have a real focus throughout the P&L.

TWST: Does the company give a great deal of attention to investor relations? Do you feel like investors have a clear understanding of what you have to offer?

Mr. Concannon: Do we dedicate a lot of time to it? My primary customer is our shareholder, and I focus there. I'm spending a lot more time with our blood center and hospital customers as well now, as we've bolstered this management team. But I very much want to make sure that our shareholders clearly understand what we're doing, why we're doing it and what it means to them. We try to be pretty transparent. So I spend as much time as I possibly can with shareholders, and then bringing shareholders here to our headquarters in Braintree to continue to convey that message and help them understand our story better. Do they understand it? I believe that there is a growing understanding and appreciation for it, certainly with our existing shareholders, and I think with the growing body of new shareholders. What we're doing here is not easy. Blood management, especially when you look at it in the blood center and hospital environment, for this to be effective people need to change the way in which they practice medicine, and that's heavy lifting. Anytime you have to introduce that type of change primarily in the surgical setting, it's heavy lifting. But the benefits both economically and clinically are huge for customers and, we feel, well worth it. Basically, we're changing the standard of care. The current focus is more on how do we scale this more rapidly and how do we help our customers to get through that change more rapidly?

TWST: Looking ahead, what might be some year-by-year indicators investors should keep an eye on?

Mr. Concannon: A couple of things here. Right now we're more focused on scaling and growing our blood management solutions. Our next major product launch will be with our automated whole blood product, which we look to bring to market in about 24 months. We certainly have to understand the regulatory requirements there, which could certainly influence that, but that's what we believe the timeline would look like. We're past most technical hurdles of this product development, which is probably the best way for me to say where we are, which involves automating the very manual process that exists today in terms of blood donations. So we're excited about what that means.

Longer term we're working on a new blood typing device with our holographic optical trapping technology that we acquired with the acquisition of Arryx back in 2006. So we think we can come to market with a device that will significantly reduce the amount of time that it takes to type blood, as well as the amount of blood and reagents required to do that. So this is a company that over the last seven years has a CAGR of 10% on the top line, 22% operating income and 19% earnings per share. As we look to the future, our aspirational goals are to grow revenue 10% to 12%, with operating income and earnings per share growing at 12% to 15% on average over the next five years.

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

Mr. Concannon: If you look at what we're doing in our space, we're kind of this behind-the-scenes, sleepy little company with about $300 million in revenues seven-plus years ago in a niche space which arguably wasn't growing. We've busted out of that environment; we're now approaching $700 million in revenue. We grew rapidly over that period of time with a clear vision and clear

strategies for the future in an industry that arguably is going to be going through some pretty dramatic changes over the course of the next several years with health care reform, but well positioned as a company that can lead in its space in helping its customers both improve economics and clinical outcomes as they navigate through those unchartered waters. We think we can help our customers to get through that to be in a better place at the end of the day.

TWST: Anything else you wanted to cover?

Mr. Concannon: When you think about health care companies today, and when you think about supply chains in the world of health care, there are very few supply chains that haven't been addressed or corrected. The blood supply chain is a fragmented supply chain, and I think we're well positioned on both the demand side and the supply side to work with our customers to improve this supply chain and its effectiveness to provide an ample supply of safe blood to patients who need it. You think about it in that fashion, in addition to everything else I said, and I think we're a company that's certainly well positioned to continue to improve and continue to help our customers get to where they need to go.

TWST: Thank you. (MJW)

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IRIS International, Inc. (IRIS)

CESAR M. GARCIA has been a Director of IRIS International since November 2003 and Chairman of the company's board since November 2007. He joined IRIS International in January 2002 as Executive Vice President; he was appointed President in June 2003 and Chief Executive Officer in November 2003. Mr. Garcia has more than 30 years of experience in the design, manufacturing and commercialization of medical devices. From 1998 through 2001, Mr. Garcia was Senior Vice President, Operations and Program Management, for Cytometrics, Inc., an early-stage manufacturer of noninvasive photonics-based medical devices. From 1994 to 1998, he was Vice President of Operations and Engineering at Datascope Corp., a manufacturer of medical devices for interventional cardiology, anesthesiology and critical care monitoring. From 1974 to 1994, Mr. Garcia worked with Bayer Diagnostics (now Siemens Healthcare Diagnostics), where he held positions of increased responsibility, including General Manager of Technicon Electronics Corp., a subsidiary of Bayer USA, and Director of Worldwide Hematology Manufacturing and Cellular Diagnostics Research and Development. Mr. García earned a B.S. in industrial engineering, cum laude, at the University of Puerto Rico, and he received an Advanced Management Certificate from Pace University.

SECTOR – HEALTH SERVICES

(ALF605) TWST: What is IRIS International? Please give us an overview and take us through each of the company's operating divisions.

Mr. Garcia: IRIS International is a global leader in the automated segment of urinalysis. However, we are much more than a urinalysis company, as we have an integral business in sample processing and an emerging business in personalized medicine. Our present customers are hospital laboratories with medium to high test volumes and high-volume clinical reference laboratories, like LabCorp, Quest, Sonic Labs and others. As mentioned, we have three operating segments, including Iris Diagnostics, with a core business in urinalysis and an active research and development program in hematology. Our Iris Sample Processing is a global leader in bench-top, rapid-processing centrifuges and DNA workstations. We have an emerging business in personalized medicine now consisting of our recently acquired CLIA-certified molecular pathology laboratory and our Iris Molecular Diagnostics group, which we acquired in April 2006.

TWST: Iris Diagnostics has been in the urinalysis testing market for over 25 years. Would you give us an example of the effectiveness of the Iris system?

Mr. Garcia: Our Iris Diagnostics Division markets complete automation in urinalysis. One of the key differentiating factors in our fully automated iQ200 urinalysis platform is our proprietary technology in digital flow imaging, by which we identify and quantify microscopic sediments in urine. We actually image the urine, while most of the competing instruments use a scattergram to represent the distribution of the urine sediment particles. The users of competing systems have to interpret those results and when they cannot make a determination from those scattergrams, a slide needs to be manually reviewed under a microscope. The competing systems with scattergrams are fast, but they have manual review rates of approximately 30%. In our instruments, we capture and digitize the images of the microscopic particles in urine and other body fluids, and calculate the concentrations of up to 12 microscopic particles. Our customers can review and edit images in our system without a microscope, and that is truly automated urine microscopy. In a typical lab, our iQ200 system provides automation and workflow improvements that result in labor savings that typically justify their capital investment, with a payback of less than two years. This product superiority has made us the global leader in automated urinalysis.

TWST: What is the market opportunity, both domestically and internationally? How is the system being marketed?

Mr. Garcia: The urinalysis market is large, approaching $500 million in annual sales worldwide. We define our addressable market as those customers that perform more than 40 urine microscopies per day. In urinalysis, there are two principal test modalities — urine chemistry and urine microscopy. Our core technology has traditionally been in the urine microscopy segment. That's the area that we have focused on, although in September 2008, we launched our automated urine chemistry system, the iChemVELOCITY, in the international market. And when combined with the iQ200, it provides a fully integrated urinalysis workstation. In the U.S. we distribute an automated chemistry analyzer supplied by a Japanese manufacturer, which we will replace with the iChemVELOCITY upon FDA clearance, which is pending.

The total addressable market for urine microscopy is approximately 8,000 sites worldwide. Of those 8,000 sites, about 3,000 sites are domestic and 5,000 sites are international. The

domestic market for automated urine microscopy is approximately 50% penetrated, and the international market is about 70% penetrated. But it is important to mention that in the international market, we have been very successful in replacing many of our principal competitors' instruments. It is worth mentioning that our principal competitor was in the market about five years before the release of our iQ200 in late 2003. We sell and support our domestic products through our direct commercial organization, and internationally we sell predominantly through distributors. But we now have direct sales in France, Germany, the U.K. and Puerto Rico.

"With the launch of the iQ200, we became a significant player in urinalysis. Since 2005 we have consistently sold between 400 and 500 iQ200 systems per year, in comparison to the 50 legacy systems per year that we sold prior to the release of the iQ200."

TWST: That said, would you tell us what current economic trends are impacting IRIS and its other businesses?

Mr. Garcia: I think 2009 was a very difficult year for most diagnostics companies selling capital equipment. Even though historically the in vitro diagnostics segment has been very resilient to fluctuations in capital availability, in 2009 we experienced a significant reduction in instrument sales as a result of the global tightening in capital availability. Our consolidated revenue in 2009 was 3% lower than 2008, but we have recovered that reduction in 2010. In the first half of 2010, we experienced a 20% increase in revenue in comparison to the first half of 2009. In today's economy, capital is more limited and more acquisition decisions are being made by hospital CFOs and their financial controllers. These executives use the financial payback as the metric to justify the investment decision. In the past, the decision-makers were lab directors, which are principally focused in clinical utility, not necessarily payback. With the shift in the decision-making process, we have modified our product presentation and the way we approach our customers, emphasizing the financial benefits of our products. Also the uncertainty in the global economies has made it more difficult to accurately forecast revenue and earnings due to currency fluctuations and capital availability.

TWST: You became the CEO of IRIS in 2003. Would you describe how the company has changed since then and what you consider to be the top accomplishments?

Mr. Garcia: IRIS is a completely different company since we released the new iQ200 platform in 2003, which coincided with my appointment as CEO of the company. At my arrival in 2002, I had to lead IRIS through a very challenging and exhausting product development schedule. By the time we released the iQ200, we had exhausted our cash and increased our debt to approximately $7 million. In the prior three years, between 2000 and 2002, we sold only an average of 50 legacy systems per year, and we had an installed base of some 450 instruments. Those systems were antiquated, expensive and difficult to service. Our international sales were only about 3% of the revenue. The management team needed to be upgraded in order to effectively compete in the industry. The manufacturing facility was suboptimal. Our reputation in the market was not the best because of the low reliability of the legacy systems. With the launch of the iQ200, we became a significant player in urinalysis. Since 2005 we have consistently sold between 400 and 500 iQ200 systems per year, in comparison to the 50 legacy systems per year that we sold prior to the release of the iQ200. We now have an installed base of more than 2,800 iQ200 systems worldwide, with recurring consumables and service revenue representing more than 50% of our total revenue.

Our revenue has grown to more than $100 million today from $28 million in 2002. We are now debt-free and have more than $30 million in cash, even after investing more than $50 million in new technology and acquisitions over the last five years. I'm pleased to report that we have just begun to see the results of these investment initiatives with increasing sales of the iChemVELOCITY chemistry analyzer and associated consumables. We continue our efforts to design, build and commercialize highly differentiated product solutions with significant high-margin recurring consumables. We are proud that a company of our modest size has been successful in competing with much larger companies. We have attained a privileged position in the market place, both in terms of product placements and with awards recognizing the excellent service that we provide to our customers. The increased clinical utility and workflow experienced by our customers due to our instruments are also key differentiators.

TWST: IRIS recently acquired the business of its overseas distributors in the U.K. and Germany. Would you explain the strategy behind this move?

Mr. Garcia: This is one of the major initiatives we undertook in 2010, and I would like to take this opportunity to clarify why this is a very strategic and important step in the execution of our growth plans. The acquisition of those distributors' business was necessary to lay down the foundation for international sales of new products expected from our core in vitro diagnostics business, as well as new products coming from our Molecular Diagnostics group, and for IRIS to take direct control of our destiny in the international market. The massive consolidation of IVD manufacturers between 2005 and 2007 resulted in significantly reduced product portfolios for many international distributors, and this was a catalyst for us to acquire the distributors' business in certain underperforming European territories. For example, since the initiation of our direct commercial operation in France in 2005, we have sold more than 130 of our iQ200 instruments. In comparison, during approximately the same time frame, our distributors in the U.K. and Germany sold only about 60 iQ200 analyzers. Although the timing of the acquisition was not ideal, we could not pass on the opportunity. We bought the distributors' asset at cost, with the understanding that we would need to invest more than $2.5 million to reinvigorate those markets in 2010 in order to establish an excellent international organization and infrastructure, which should result in significantly greater sales of our products in the international marketplace and with greater profit margins, as well as provide a foundation from which to launch the new products that we are planning over the next five years. So with this implementation, we will sell direct in most of

the major European countries with the exception of Italy and Spain.

TWST: The company recently acquired AlliedPath, a private CLIA-certified lab that's focused on oncology and molecular diagnostics. What did that acquisition add to IRIS? How did it factor into the company's overall growth strategy?

Mr. Garcia: Let me step back for a moment. In 2006 we acquired our NADiA ultra-sensitive nucleic acid detection immunoassay technology platform to enable the early detection of residual diseases, such as cancer relapse and HIV breakthrough. Since then, we have invested some $30 million in funding this business and the related R&D initiatives in developing our NADiA product line. We acquired AlliedPath in July 2010 primarily to provide a direct commercial channel for accelerating our NADiA platform. The first test we have developed under the NADiA platform is NADiA ProsVue, our prostate cancer prognostic test, which is currently under FDA 501(k) review. Our CLIA laboratory acquisition not only enables the distribution channel for NADiA ProsVue, which we plan to launch as soon as it receives FDA clearance, but it also provides a commercial platform to sell most of the other NADiA-based products we are developing, including the NADiA HIV viral load test, a NADiA test for breast cancer and other NADiA applications. In addition, we believe there is an opportunity to license our NADiA technology in order to generate higher earnings, and increase the acceptance and utilization of the technology.

This strategic acquisition positions IRIS with a state-of-the-art, fully equipped, high-complexity, CLIA-certified molecular pathology laboratory, offering differentiated, high-value molecular diagnostics tests and services. The laboratory currently offers molecular mutation testing for solid tumors, including lung and colorectal cancer, and is expected to add breast cancer by the end of the year. In addition, IRIS is planning to add flow cytometry for detection and monitoring of leukemia and lymphoma, and will add FISH testing to augment the laboratory's test menu. We believe the molecular pathology and personalized medicine market is growing very rapidly within the esoteric laboratory services and tests segment, a market which, in the U.S., is expected to grow to $21 billion annually by 2015, from $11 billion in 2009.

It is our intention to strengthen the relationship between our molecular diagnostics development group and our CLIA lab to accelerate the release of new NADiA applications and to build a relationship with pathologists, urologists and other health care professionals in order to deliver personalized medicine solutions. We also believe the CLIA laboratory, in addition to being an anticipated source of additional revenue and earnings, allows us to better control critical commercial decisions, such as a value-based pricing strategy, marketing, communication programs and other commercial priorities. We expect to gain access to patient samples that are difficult to obtain otherwise. So it will help us accelerate product development and obviously will keep us closest to the clinical decision-makers and the clinical users, which is something that is very important in the early stages of launching a product platform like NADiA.

I believe the acquisition is very strategic for these and many other reasons. While this acquisition will be dilutive in 2010 and 2011, we do expect to reach breakeven in 2012. The gross margins for this new business are expected to range between 70% and 80%. We have hired an experienced and highly competent management team to run this operation, and we are confident our targets are achievable.

"It is our intention to strengthen the relationship between our molecular diagnostics development group and our CLIA lab to accelerate the release of new NADiA applications and to build a relationship with pathologists, urologists and other health care professionals in order to deliver personalized medicine solutions."

TWST: Is growth basically in-house generated, or would you look at strategic opportunities, i.e., M&A, personnel, products or alliances?

Mr. Garcia: I think that mergers and acquisitions are important for us. I think that we can benefit significantly by adding more products through our existing commercial organization and increasing our scale. We have an award-winning customer service infrastructure with direct field service and support that can synergistically benefit from adding more products to our current offering. However, we do not want to become a portfolio company with products that are not directly related. We want to maintain the focus in image morphology with applications in urinalysis, hematology and personalized medicine. We also have a Sample Processing division with the bandwidth to absorb more product lines. We are looking for product lines or companies that would bring incremental revenue and earnings, and potentially enable us to get our product pipeline to the market faster. With that said, we are only focusing on accretive acquisitions at this point in time.

TWST: Turning to your top management and internal operations, do you have any plans to change any of these areas? Are there perhaps specific needs you will address over the next year or so?

Mr. Garcia: Over the last year, we added senior management talent to address some of our weaknesses. Late in 2009, we hired a new Vice President of Corporate Quality and Regulatory Affairs and a new Vice President of Research and Development for the Iris Diagnostics division. We restructured the sales management team, both domestic and international, adding a Vice President of Sales for America and several country managers in support of our direct sales initiatives abroad. Our restructuring of the sales organization is intended to put more emphasis in Europe and to cope with the changing economic environment. This increase in sales staff is partially responsible for the significant increase in sales we have achieved in the first half of 2010.

Most recently, with the acquisition of our molecular pathology laboratory, we hired a President for that division, and as a part of that acquisition, one of the founders of AlliedPath joined our management team as Chief Medical Officer, a newly created position at IRIS. Both of these executives will have a very

significant role in the launch of our new business in personalized medicine. I am very proud of the quality of the management team. We're a $100 million company with a management team that comes from very large in vitro diagnostics companies and is committed to delivering our growth plans. We all have experience in multibillion-dollar global companies. We have revamped our senior management team, as it was necessary to achieve more predictable outcomes in terms of product launches and financial performance. I am confident we now have the breadth and depth in the management team to more consistently meet our commitments.

TWST: Last month you announced the highest-revenue quarter in the company's history, with second-quarter revenue up 19% from the same period last year. What made this year's second quarter such a success?

Mr. Garcia: We have been working very hard in increasing our sales funnel globally, and in streamlining the sales organization and enhancing our iChemVELOCITY. I think that we've fine-tuned the sales message so we not only talk about the clinical advantages of the instrument, but also talk more about the financial benefits generated by our products. I believe there has been a recovery in the IVD market, where the hospital and clinical reference lab customers are more confident about the general economic outlook, something that has definitely helped us in achieving record revenues during the last nine months. In addition to that, we have had very strong consumable sales over the same period. In 2009 we worked very hard in relaunching our iChemVELOCITY urine chemistry analyzer in the international market, and it has begun to produce results in 2010 by generating incremental consumables and absorbing excess capacity in our strip manufacturing plant in Marburg, Germany. Also in the first half of 2010, our domestic sales were much better than last year, part of which is related to the availability of capital, and we have been more effective in getting some of that capital.

TWST: What was the motive behind IRIS' recently approved $10 million share repurchase program? Why do you consider a share buyback program to be a good use of capital at this time?

Mr. Garcia: We decided to implement a stock buyback program because we believe the intrinsic value of IRIS at this time is much greater than what is reflected in the current stock price. We wanted to send the message that both the management and the board of directors are confident that we can execute on the plans that we have ahead. We believe the recent decline in our share price is a reflection of the delays in attaining FDA clearance of our iChemVELOCITY and the NADiA ProsVue, and believe our market capitalization should improve as these products receive anticipated approvals in the near future. The other reasons for the recent stock performance relates to our decision to re-invest cash from operations to finance significant investments, which are expected to be very good for the long term but are dilutive in 2010 and 2011. For example, this year we are investing $2.5 million in regrowing the international distribution organization. In addition, we are investing $5 million in molecular diagnostics and obviously with our recent acquisition of AlliedPath, where we invested an initial $4.7 million in cash for the acquisition, and committed to invest another $2.5 to $3.0 million in the commercial launch of the new CLIA laboratory.

We have a core business that is producing significant earnings, and we opted to reinvest those earnings in growth that we could not achieve otherwise. I believe that is the right move at this point in time. IRIS has been sitting on a significant amount of cash without putting that cash to use, and I do not believe that serves the shareholders in the long run.

TWST: In your discussions with the investment community, are there any recurring questions or misperceptions? Does the investment community understand the IRIS story?

Mr. Garcia: I think the investment community does not fully understand our strategy, and they are very concerned with our products attaining regulatory clearance. We are optimistic about attaining clearance on these new products soon. One of the recurring questions relates to the release of the new products and the attainment of FDA clearance for the iChemVELOCITY and the NADiA ProsVue. There is much concern with the strict requirements imposed by the FDA, which are beyond the control of the company's management. The regulatory environments have changed dramatically over the last two years. In the past, our products were cleared in a timely manner, but more recently the FDA has become much stricter and they have heightened the clearance requirements. The FDA is in the process of redefining the 510(k) process, and we have been reacting to their changes in policy, something that has affected many manufacturers' ability to get their products cleared under 510(k)s. That's one of the biggest concerns. Myself, as CEO, the board of directors and the management team share some of those same concerns, but we are addressing this methodically and consistently, as we did with our recent success in attaining clearance for our synovial fluid 510(k) application.

The other recurring theme is the rationale for our investment in molecular diagnostics and personalized medicine. Some shareholders feel that we should remain in the core morphology business only. We believe that the company has greater potential by diversifying into personalized medicine and diversifying the core urinalysis product line into hematology. We have been running the company for the long run. With that said, we have enough in our product platform at this time, and we do not intend to make any additional technology acquisitions in the near future. We are now placing much more emphasis on shareholder return because most of the recent strategic initiatives have been dilutive, and we want to demonstrate that the investment in these new product initiatives are commercially progressing and beginning to create value for our customers and shareholders.

We have been very successful in generating significant incremental revenue over the last five years. The company's compounded annual growth rate of revenue has been more than 18% since 2002. If you exclude the investment in molecular diagnostics and the laboratory, the compounded annual growth rate of earnings since 2002 on an adjusted basis is approximately 35%. The management team has proven that we can execute commercially, and we expect the investment in our product pipeline will prove to be successful through future earnings generation.

The other concern that the shareholders have is whether we are going to continue the trend of dilutive acquisitions, and the answer is no. We are looking for product opportunities that can

synergistically benefit from the infrastructure we have established, so we can gain financial leverage. Our general concept is growth at a reasonable price. That is what we are planning to achieve over the next few years.

TWST: Are those the key metrics for investors to focus on?

Mr. Garcia: I think the key metrics are, number one, maintaining the momentum in the sales of our existing core product. We have been successful in recovering our sales momentum in 2010 versus 2009. Number two is getting clearance for iChemVELOCITY and NADiA ProsVue. Those two product clearances are very important. Our third priority is to complete an integrated prototype for the new image-based hematology analyzer and accelerating the development of our next-generation urinalysis system in 2011. Finally, on the personalized medicine side, it is our objective to achieve our revenue and growth targets for the laboratory in 2011 and achieve breakeven in 2012.

TWST: In conclusion, what is your summary statement? What should compel investors to include IRIS as a part of their current portfolios and longer-term investment strategies?

Mr. Garcia: IRIS is a company with a track record in growth and innovation. We have grown the company from $28 million in revenue to over $100 million between 2002 and 2010, and we are confident that we can focus on earnings generation now that our technology acquisitions are behind us. We have the management team to execute on our future plans. The company has a solid core business that continues to generate revenues and earnings, and an emerging business in personalized medicine and molecular diagnostics. I believe the current valuation of the company does not reflect the value of our new product pipeline under development. Our plan is to change that by attaining clearance on our pending regulatory applications and consistently achieving our strategic and financial milestones.

TWST: Thank you. (KL)

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Ophthalmic Imaging Systems (OISI.OB)

GIL ALLON has served as Ophthalmic Imaging Systems' Chief Executive Officer since September 2000 and as a member of the board of directors since August 2000. He previously served as the Vice President and Chief Operating Officer of MediVision from June 1993 through August 2000. Mr. Allon received his B.A. and M.Sc. in computer science, both with distinction, from the Technion Israel Institute of Technology, in Haifa, Israel, in May 1987 and December 1989, respectively. He received his MBA with distinction in business management from the University of Haifa in September 1999.

SECTOR — HEALTH SERVICES

(ALF606) TWST: Please begin with a brief historical sketch of the company and a picture of what you are currently doing.

Mr. Allon: Ophthalmic Imaging Systems, or OIS, was founded in 1984 to harness the capabilities of the emerging field of digital imaging to assist eye care professionals with diagnosing patients more efficiently and effectively. After establishing a digital presence in the majority of retinal institutions, OIS began several years ago to grow by integrating all of our diagnostic devices within the practice into a single cohesive solution and becoming the most successful PACS, picture archiving and communication systems, provider within the eye care industry. OIS is now positioned to provide unprecedented services to the eye care field. We are now the only company to provide digital imaging, image management, EMR/practice management and diagnostic imaging solutions.

TWST: So you've broadened your offerings over time?

Mr. Allon: Yes, we evaluated our business and the market opportunities a few years ago and expanded from one product line to the four different product lines I mentioned — digital imaging, image management, EMR/practice management and diagnostic imaging solutions.

TWST: Of the different product lines and business areas, which is the largest and where do you see the potential for the most growth over time?

Mr. Allon: Actually, the four product lines are relatively similar in the revenue mix. Three product lines are 20% or above of our revenues. We have a fourth product line, which we introduced just this year, and it already accounts for more than 10% of our revenue in the first six months. The fifth offering, while not a product line, is a revenue stream — annual service contracts. So we have a good revenue split among four product lines and our service income, which provides for well-balanced revenue potential. Out of those, the three fastest growing are the EMR/practice management system, which emphasizes EMR; OIS EyeScan, which is a new product we launched this year; and Symphony, which is our image management.

TWST: Tell me about your background as the CEO of the company.

Mr. Allon: I have a Master of Science degree in computer science, and I have an MBA. I have more than 20 years of managerial experience mostly in the ophthalmic or eye care field. I have been the CEO of OIS in the last 10 years.

TWST: How would you describe the outlook for the industry and for your company in particular at the moment?

Mr. Allon: Eye care in general is undergoing a transition, where more diagnostic testing and basic treatment are moving to the optometrist level, with ophthalmologists increasingly specializing in single, complicated diseases. At OIS we have positioned ourselves to survive and thrive within this changing environment by providing diagnostic imaging solutions, like OIS EyeScan, which allows for seven different image types to be captured with an approximately $20,000 device. That's less than half of the cost of comparable technologies. In addition, the OIS Symphony Image Management System is the only eye care PACS that facilitates the referral process toward the use of automatic, secure EMR-based access, enabling our customers to move diagnostic images and reports from one level of the curve to another with a single click.

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

Mr. Allon: We have four product lines, as I mentioned. Each product line has a different set of competitors. On the EMR/practice management product line, we have more than a few, including EMR and practice management companies. Some of the larger companies in EMR are working mostly with the hospital level and across the health care fields. We are working more in the ambulatory care market. We have a few competitors, which are mostly private, relatively small companies. With WinStation, our ophthalmic imaging system, and the OIS EyeScan, our new imaging system we launched this year, as well as a complete software and hardware package, we compete against other device companies in ophthalmology. The larger of these are Zeiss and Topcon. Zeiss is a German company and Topcon is a Japanese company. With Symphony, our image management system in ophthalmology, we clearly are the market leader and Topcon is our main competitor.

TWST: Generally speaking, what do you see as some of your competitive advantages?

Mr. Allon: I believe we have competitive advantages in each product line. First, we have a unique product with our OIS EyeScan. There is no competing product that has the combined functionality of the product — seven different modules that allow seven different applications for imaging the front side and back side of the eye. It can be used as a portable or stationary device. No other product offers this combination of features. Second, our EMR is

special relative to our competitors in ophthalmology; it is chart based, making it very true to the workflow in ophthalmology. At OIS we focus solely on ophthalmology. We also sell the EMR through our subsidiary, Abraxas Medical Solutions, in three other medical specialties outside ophthalmology – OB/GYN, orthopedic and primary care. In Symphony, we also have several features that are unique to our product.

"For two years, we invested heavily in R&D, much more than had been our norm. This year we are investing more than the norm into marketing. We are successfully gaining momentum from each of our four product lines, and this is showing in our revenue growth compared with the previous year."

TWST: The OIS EyeScan launched in the last 12 months or so. How is that going?

Mr. Allon: It's going very well. We launched it at the end of last year, at the largest meeting in the eye care field. We started to take orders, and we began shipping in the first quarter of this year. We are gaining momentum every quarter. We are currently in the third quarter following launch and sales have been stronger than the previous quarter.

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

Mr. Allon: Although our debt-to-equity ratio weakened with our losses and taking on bank debt during the recession, we strengthened our balance sheet with an equity investment by AccelMed and by the conversion of some debt into equity. It's a good sign for growing the company to be financing our operation from equity versus debt at this time. Also one thing to note is in the first half of this year, our revenues grew by 68% relative to the first half of last year.

TWST: Speaking of year earnings, your August statement showed improvement across the board. What were some of the keys to the improving sales, a significantly smaller loss and better margins?

Mr. Allon: I would say in general it's the fruit of the last three years of heavy investment and our effort to continue to become a company with multiple product lines. At the end of last year, we launched the OIS EyeScan. We added more features to our Symphony, and we started to gain share in the EMR/PM market. For two years, we invested heavily in R&D, much more than had been our norm. This year we are investing more than the norm into marketing. We are successfully gaining momentum from each of our four product lines, and this is showing in our revenue growth compared with the previous year. We reported a loss as a result of our investment, which is in line with our plan to increase our sales and marketing. By looking at our financial results, you can see that our marketing expenditures were higher than in the past, but we expect these expenditures to pay off, and we are confident we have the right team to support our growth.

TWST: Also in your last earnings release, you mentioned the adoption of informatics solutions should accelerate following the July release of the final rule of meaningful use for electronic health records under the American Recovery and Reinvestment Act. What does that law mean for your company?

Mr. Allon: The package, which is part of the stimulus plan announced more than a year ago, allocates about $20 billion for physicians rather than for companies. Under this package, the federal government is supposed to pay each doctor up to $44,000 when they become a "meaningful user" of an EMR system. In the last year, we didn't see much traction in the EMR market because the rules and regulations were not completely clear. The federal government was working on the specifics to define all of the small details. What are physician requirements to comply? What kind of software will meet the requirements? How will the software be certified? Which institution will certify the software? All this created some uncertainty in the market. Physicians are not planning to buy and implement the EMR until they know that the details are final and everything is clear. In the last few weeks, the "meaningful use" and the "certifying bodies" have been defined, but it will take some time until the uncertainty is totally removed. We believe that in the next few months or so, the remaining uncertainty will be removed. We of course are committed to meeting all the requirements that will allow doctors to become "meaningful users" by using our software.

TWST: Tell us about Abraxas Medical Solutions and the role it plays in the company's potential success.

Mr. Allon: I think it's common knowledge that the EMR field in the United States is going to grow very significantly in the next few years because of the stimulus package and even more because the U.S. is actually behind the rest of the Western world in implementing and adopting EMR systems. So we believe this boom of EMR — all medical field becoming paperless or using EMR in a significant manner — will happen in the next decade, with the stimulus or without it. With the stimulus, it will happen faster. So in preparing for this market boom, two and a half years ago, we established a subsidiary called Abraxas Medical Solutions. We bought the assets from another company, mainly a source code for an existing EMR, and with management from this company we started our own EMR business. As OIS is a strong entity in ophthalmology, OIS sells this EMR product with modifications required for the eye care market, while our subsidiary, Abraxas, is selling it to a few other medical fields outside ophthalmology. Together we have a presence in multiple medical fields using the same platform. In this growing market, we believe our potential should be very high.

TWST: What are the long-term goals for OIS? How big do you want to get?

Mr. Allon: Our strategy is to build our business. We have a five-year internal plan, which we are constantly updating. While we are not discussing specifics of this plan, we can say that we are focusing on significant top-line growth and profitability.

TWST: Does the company give a great deal of attention to investor relations? Do you feel like people have a clear understanding of what you have to offer?

Mr. Allon: We are currently renewing our efforts to focus investors on the opportunity with OIS. We believe this is the appropriate time, given our business expansion into four product

lines, our growing revenues and the future growth potential in the markets we address. This interview is part of such an effort.

TWST: Moving forward, what might be some year-to-year milestones or indicators that investors should look for going forward?

Mr. Allon: I think investors should monitor our ability to generate revenue growth from our expanded product offering.

TWST: What is the role of UM AccelMed? They helped you raise about $6 million in capital, and they own 42% of the company.

Mr. Allon: AccelMed invested last year and this year $6 million in OIS. In addition to funding, AccelMed participates in board meetings and some other management meetings. They provide assistance and expertise. Should we find a specific target for acquisition or merger, or any business transactions that we believe will be beneficial for the company and our shareholders, it's very reassuring to have such a financially strong institution as part of our board standing behind us.

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

Mr. Allon: We offer products with competitive advantages that address two growing markets, EMR/practice management and ophthalmic imaging. And OIS is a leader in ophthalmic imaging, with an established customer base that we can leverage. We offer our new OIS EyeScan that addresses our established customer base as well as eye care specialists who are not our current customers. Health care demand and the stimulus plan are driving EMR sales growth, and we are expanding EMR sales into additional medical specialties, which are addressed by our subsidiary, Abraxas Medical Solutions. As a final point I would say that OIS has the infrastructure to support growth, both from a managerial and financial perspective.

TWST: Thank you. (MJW)

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Vicor Technologies, Inc. (VCRT.OB)

DAVID H. FATER joined Vicor Technologies, Inc., in 2002, and he also serves as Chief Executive Officer of ALDA & Associates International, Inc., a business and financial consulting firm specializing in health care and life sciences. Prior to joining Vicor, Mr. Fater held senior executive positions with three public health care companies. He led the initial public offering process for BMJ Medical Management, Inc. (1997-1999), and Community Care of America (1995-1996). He also led Coastal Physician Group, Inc. (1993-1995) to a NYSE listing and $1 billion market capitalization. Previously, Mr. Fater was employed by Ernst & Young, where he completed his 24-year tenure as a Senior International Partner advising senior management and boards of directors (1969-1992). Mr. Fater is a certified public accountant in Georgia, Illinois, North Carolina and New York. He holds a B.S. in accounting from the University of North Carolina.

SECTOR — HEALTH SERVICES

(ALF602) TWST: Would you start with a brief historical sketch of the company and a picture of the things you are doing at the present time?

Mr. Fater: Vicor has been in existence for 10 years. We celebrated our 10th anniversary on August 11. In a lot of respects, that's a major accomplishment because there aren't too many startup biotechnology companies that can say they've lasted 10 years. In that 10-year span, we've managed to develop some significant, breakthrough medical diagnostic technology and actually had our first product introduced into the marketplace in 2010. Our products provide a new measure of heart rate variability that enable physicians to accurately put their patients in one of two buckets — high risk, low risk — and do that easily. Importantly, physicians are able to receive reimbursement from public and private insurers under existing procedural codes for tests performed using our products. So from both a financial perspective and a clinical perspective, the physicians find this technology very worthwhile.

We're focused on three areas right now. The first of these is autonomic nervous system dysfunction, which is a co-morbidity complication of diabetes. There are 24 million diabetics in the United States, and that number is growing significantly. The American Diabetes Association has recommended diabetics receive annual screening for autonomic nervous system dysfunction. We're also focused on cardiology. There are 81 million patients in the United States with cardiovascular disease. And we also have a technology for triaging trauma patients that we're developing in collaboration with the United States Army.

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

Mr. Fater: I spent 24 years as an International Audit Partner at Ernst & Young, and when I left them in 1992, I went into health care and became the CFO of three public health care companies, two of which I took public, one of which I took to the New York Stock Exchange. I was recruited to Vicor by the founding scientists in 2002. The inventor of our technology was the first Ph.D. in neuroscience from UCLA in 1967. His lifelong area of study has been detecting how the brain and the heart are connected in such a way that the brain really controls irregular heartbeats and ultimately fatal arrhythmias. Most physicians just focus on the heart and the health of the heart. He was hired out of UCLA by Dr. Michael DeBakey at the DeBakey Heart Institute, where he spent 24 years as a full Professor of medicine at Baylor. And that's where he performed his seminal experiments and actually developed the science behind our technology. Our Vice President of Product Development is Dr. Jerry Anchin, a Ph.D. from Texas A&M. Jerry spent 25 years in Southern California in drug discovery, diagnostics and medical devices. Our Chief Operating Officer is Dr. Richard Cohen, who has spent 30 years in worldwide sourcing and operations and is a key relationship person for a lot of the international deals we're negotiating, as well as our relationships with several important universities where we conduct clinical trials. Our Chief Medical Officer is Dr. Daniel Weiss, who's an electrophysiologist and electrical engineer by background. Danny left his practice three years ago to join us full time as our Chief Medical Officer. Our Chief Technology Officer is Lloyd Chesney. Lloyd has constructed what we believe is a very unique delivery model for both the physician and the health care community.

In addition to these individuals, we have a scientific advisory board that provides direction to the company on where the science should be concentrated. These individuals are considered the world's thought leaders in their areas. For example, Mark Josephson is a member of our scientific advisory board. He is the Chief of Cardiology at Beth Israel Deaconess Medical Center, in Boston at Harvard, and the author of *Clinical Cardiac Electrophysiology*, the single-authored textbook that's used in every medical school in the country. His counterpart in Europe is Dr. Hein Wellens. Hein is also on our scientific advisory board. Between the two of them, they've authored 24 textbooks and 1,000 manuscripts. We also have Dr. Bob Hauser, who is a Senior Cardiologist out of

Minneapolis and CEO of Cardiac Pacemakers, an implantable device company that was acquired by Guidant, which is now Boston Scientific. We also have Jonathan Kaplan on our scientific advisory board. Jonathan is the Medical Director for Fidelis Care, in New York. Before that, he was the Medical Director for Excellus BlueCross BlueShield. His background brings an insurance perspective to our company. We also have Dr. Ed Lundy. Ed is the Chief of Cardiothoracic Surgery at Good Samaritan Hospital in Suffern, N.Y., and a Class I trauma surgeon. The members of our scientific advisory board are in the disciplines we're targeting, and they're thought leaders other physicians listen to.

"Physicians are extremely gun-shy about introducing new technology, especially technology that's going to cost them money. That's why we've constructed a business model with an interesting delivery mechanism that really should appeal to most physicians' need."

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

Mr. Fater: That is an interesting question, given the times and circumstances. First, let me start off by saying I think our prospects are excellent because of our technology and the fact that physicians want it and will want to use it in both their practices and in hospitals. The reason that's an interesting question is the prospect of health care reform, which has really shaken physicians, and they've had their Medicare payments withheld three times this year as a result. Up until the end of last month, they were facing the prospect of a 20% cut in their Medicare reimbursement rate. So physicians are extremely gun-shy about introducing new technology, especially technology that's going to cost them money. That's why we've constructed a business model with an interesting delivery mechanism that really should appeal to most physicians' need for additional clinical information and the need to conserve cash while increasing their practice revenue.

A lot of medical devices for physician practices cost a physician, out-of-pocket, $30,000 to $40,000 up front. That is a huge hurdle for a lot of physicians. And for the device company, there is no recurring revenue stream; it's a one-time sale. We take a different approach. We sell the PD2i ® Analyzer, which consists of a laptop computer paired with a digital ECG via a USB cable that collects the ECG data for our analysis, with an automated blood pressure collection built into the software for $6,500. We then charge the physician a per-test fee for analyzing the ECG data and producing a report for him to interpret and make a diagnosis. At the end of the collection period, the software automatically via the Internet sends the data file that's been collected during the test to our remote server, where our software analyzes the data, produces an electronic health record with the report and the billing information for the doctor, and transmits it back to that laptop in a period of about 60 seconds. So the physician has an electronic health record that's compatible with the EMR he is being pushed to generate to conform with health care reform goals. It has the information he needs to interpret the report and make the diagnosis of the patient, and he has the information needed to bill the insurance company. The cost of the hardware is modest — if physicians don't pay something, they'll think it's a toy and not use it — but by no means prohibitive. And then we receive a recurring source of revenue that comes from the performance of each test.

TWST: What's the competitive landscape like?

Mr. Fater: We are aware of one competitor in the autonomic nervous system marketplace. They have a $45,000 piece of equipment and no recurring service revenue. And at the end of five years, the physician has to pay another $25,000 to relicense the software. We know they've got an installed base, although not necessarily a large installed base. We also know, given the current health care reform landscape, that physicians who don't have this equipment today are less likely to get it because of that upfront cost. That's the only competitor we have in the ANS arena.

In the cardiology arena, there's one competitor: Cambridge Heart. Cambridge Heart is a publicly held company with a T-Wave alternans test for assessing the risk of sudden cardiac death. This machine also costs $45,000, plus the physician has to buy single-use, special-purpose electrodes that cost $80 a pair, for which he's not separately reimbursed. And their test requires a treadmill and a stress test, which introduces all sorts of complications that really render the test of small interest to physicians. Requiring a sick patient to complete a stress test introduces the risk of cardiac arrest. So the physician has to be present, the nurse has to be present, the technician has to be present, a crash cart has to be present, and it takes 20 to 30 minutes to do the test.

Our test, by contrast, is a 15- to 20-minute test in which the physician's only involvement can be the writing of a prescription to authorize the test. The test can be performed by a technician. The physician's next involvement is to review the final report and make the diagnosis. There is no treadmill involved. It's a resting ECG with the patient performing three standard of care maneuvers for an autonomic nervous system dysfunction diagnosis. These maneuvers are metronomic breathing, a Valsalva maneuver, which is a forced exhalation, and two minutes of changing from a recumbent position to a standing position. That's the entire extent of the test.

TWST: You launched your first product in January?

Mr. Fater: That's correct.

TWST: How are things going sales-wise?

Mr. Fater: Sales have been slower than expected. This is partially because from a company standpoint, we've never been appropriately capitalized. So when we launched this product, we had an opportunistic agreement that enabled us to put in place 25 independent sales reps in North and South Carolina, and we had one other internal person involved in selling. All of this was geared around our going to the markets to raise some capital. We have an S-1 on file that covers raising as much as $10 million, which would primarily be used to drive sales and marketing. As a result of what transpired in the second quarter with health care reform and the physician community, getting the product out has not been as fast as we'd have liked. We've seen some activity and are seeing more encouraging activity in the third quarter. We're in the process of

signing up additional distributors. We hired a national sales manager two weeks ago. By the middle of the third week in September, I believe we could have at least 12 or so additional distributors and their sales representatives pounding the pavement with minimal cost to Vicor. Of course once we get our funding squared away, we can hire additional company sales personnel in select areas. I don't intend to have a Pfizer-type sales force; we will be using a hybrid-type sales force consisting of company sales personnel augmented by distributors and independent sales reps.

TWST: What's the time frame for raising money?

Mr. Fater: Fourth quarter or early in the first quarter of 2011.

TWST: Is it a platform technology for several devices?

Mr. Fater: It's a platform technology for applications. Many of the physicians on our scientific advisory board believe we're measuring the key to metabolic syndrome, which is really the key to health. For example, we've demonstrated in our clinical trials, which have not yet been reviewed by the FDA, that we're able to identify trauma patients — whether they're soldiers or civilians — who are at imminent risk of death and need to have what's called a life-saving intervention performed on them immediately. In the cardiology area, we just completed a major clinical trial, the MUSIC Trial, with the University of Rochester and the Catalan Institute of Cardiovascular Science, in Barcelona, Spain. The MUSIC Trial studied 537 congestive heart failure patients over 44 months. Our PD2i technology was able to retrospectively identify those patients at elevated risk of cardiac mortality and pump failure mortality with a hazard ratio of better than 2 to 1 and a p-value of 0.004, which is almost statistical certainty. That abstract has been submitted by the researchers for publication and has been accepted for presentation at the 2010 Heart-Brain Summit at the Cleveland Clinic later in September.

In December of last year, we conducted a study to test the ability of the PD2i to detect acute hypovolemia in blood donors as a preliminary step toward determining whether the PD2i could be a useful noninvasive diagnostic for detecting blood loss from internal bleeding. The study was conducted in cooperation with the University of Mississippi Medical Center and Mississippi Blood Services. All 18 participants in the study were tested prior to donation to determine a baseline PD2i value, and retested during and after collection. The average PD2i value of participants prior to donation was 2.60; the average PD2i value following donation was 1.80. With a p-value of 0.001, the study results are highly statistically significant; this indicates a better-than-99% probability that the results were not achieved randomly. An abstract of this study was accepted for presentation at the AABB 2010 Annual Meeting in October.

On August 7 of this year, we filed a patent for our ability to analyze respiratory waveforms and identify which of those patients on ventilators may be safely removed from their ventilators in order to avoid having a patient removed from the ventilator only to then require re-intubation to be put back on the ventilator.

Our technology is capable of analyzing any series of biological data collected over time; which is unique. We have an anesthesia study that we'll be starting shortly in which the PD2i will be used in the operating room as a continuous monitor to provide an early warning to the anesthesiologist and surgeons that a patient is about to crash. The ability to identify the risk of crash would lower fatalities during surgery. We're attempting to accomplish the same thing in an ICU unit: identify which patients are safe to discharge to a step-down unit. We are also conducting a study of patients with severe brain trauma in the neurological ICU unit at the University of Mississippi Medical Center to identify those patients who may recover well and those who may not. So we have a wide variety of applications for our technology. What we ultimately hope, with enough studies and use, is to establish the PD2i as a new vital sign to be used alongside the current standard vital signs of pulse, blood pressure, heart rate, respiration and temperature.

"Many of the physicians on our scientific advisory board believe we're measuring the key to metabolic syndrome, which is really the key to health."

TWST: So over the longer haul you see a lot of potential and a very broad application?

Mr. Fater: That's correct.

TWST: Your investor presentation said that you had some products that you were hoping to get 510(k) clearance on in the first half of this year. How is that coming along?

Mr. Fater: On July 1 we filed a 510(k) for a cardiac claim based on the results of that MUSIC Trial. It is currently under FDA review. We're also hoping to submit our 510(k) for a trauma application before the end of this year. We're currently trying to obtain additional clinical trial data and reviewing the 325-patient data sets we already have. So we are hoping for additional applications and clearances. That said, I'd like to make sure it's perfectly clear: with the marketing clearances we already have, we have the capability to generate a substantial amount of revenue. Although we currently have only nonspecific labeling for the measurement of heart rate variability, some physicians are using our technology in the cardiology arena based on the data we've published.

TWST: You mentioned briefly building a bigger sales force. What have you got going on internationally?

Mr. Fater: We are currently in negotiations with distributors in the Far East, the Middle East, Israel and Europe, and South America. Some of those agreements should come to fruition shortly.

TWST: Your investor presentation also says that you sell high-margin, high-operating-profit products. Would you tell me a little bit more about that?

Mr. Fater: The hardware, which is the $6,500 component, has a margin in the 30% range. The test fee — we charge $40 a test — has a 70% margin. Our revenue model is driven by the higher-margin test fee, not the lower-margin hardware sale. In other words, revenue from test fees increases exponentially based on the number of analyzers in use and how often they're used.

TWST: That presentation also says you offer a substantial cost-savings, public and private insurance. Would

you explain that a little bit more?

Mr. Fater: There are at least two ways currently in which our technology provides a cost-savings to insurers and the health care system as a whole. The first — using the cardiology claim we're currently seeking as an example — involves the cost of implantable cardioverter defibrillators. The current treatment for congestive heart failure patients and ischemic patients at risk of sudden cardiac death is implantation of a $100,000 automated implantable cardioverter defibrillator or ICD in the at-risk patient. The ICD "shocks" the heart into normal rhythm when it fails to maintain normal rhythm on its own. Published studies reveal that 76% of the people who have received an ICD have never experienced a shock, which means they didn't really need it. Yet 80% of the people who die every year from sudden cardiac death don't meet the current criteria for an ICD. So you have complete chaos in the area of risk stratification technology to enable proper identification of those patients. Patients are aware of this dilemma and resisting physician recommended implantation. The defibrillator companies are in a complete state of stagnancy.

Where we think we can help the Medtronics, Boston Scientifics and St. Jude's of the world is to, "A," identify those patients who are at risk for cardiac mortality but don't meet the current criteria for a device and "B," identify those patients who might meet the criteria for a device but don't really need one. It takes a lot of $160 to $200 tests before you've run up the cost of implanting a $100,000 device in somebody who doesn't need it. Now I understand that we need a lot more data before the insurance companies are going to go out on a limb, given the existing criteria, but that's coming because there is wide acknowledgement that the current criteria isn't accurately identifying those in need of an ICD. So that's one way we think we can save the health care system money.

The second way is by providing a test that enables physicians to identify diabetic patients with the early stages of autonomic nervous system dysfunction and do something about it. The ability to minimize the impact of ANS dysfunction, which leads to co-morbidity such as silent heart attacks, stroke and kidney failure, is huge. Diabetes itself is not the problem. The problem is the co-morbidity resulting from the disease when it goes unchecked and untreated. Heart rate variability is the standard of care for identifying diabetic autonomic neuropathy, which is ANS dysfunction in diabetics. I'll give you a different example from a past life. When I was with a different company, we had 70,000 Medicare enrollees in Southern Florida, for which we were at full risk, meaning we were at risk for all of their health care — just like an insurance company. They paid us the insurance company portion of their premium, and we were responsible for their health care. If we had a diabetic patient, we insisted they come into the clinic once a month whether they needed to or not. If they did not come in, we invested the extra money to send a van to their home and bring them into the clinic, because the cost of that clinic visit could potentially save a $100,000 hospitalization. Preventing a diabetic from crashing either through noncompliance with diet and medication, or some complication that would have been spotted in a clinic visit and otherwise wouldn't have been spotted until they hit the emergency room, was well worth the effort and the cost. That's how I view our technology. We can stave off economic disasters by identifying those patients at risk, properly treating those patients and managing those patients not truly at risk more conservatively at a lower cost.

TWST: Are you forecasting profitability at any point? What's it going to take to get there?

Mr. Fater: I think we should get there at the end of 2011.

TWST: Does the company give a great deal of attention to investor relations? Do you feel people have an understanding of what you have to offer?

Mr. Fater: I do pay a great deal of attention to investor relations, but I don't feel that a lot of people understand what we have to offer. I can't put my finger on it. I've got several different investor relations efforts going on. We work with a traditional investor relations firm, which puts us in front of institutions every month. We're also working with other sources that help us get in front of the retail investor, who I think our stock will appeal to. As brokers no longer have discretionary authority with Bulletin Board stocks, this is very important.

TWST: Looking ahead, what might be some year-by-year milestones or indicators that investors should look for when keeping an eye on Vicor Technologies?

Mr. Fater: The first of these are additional 510(k) clearances. Following that is increased revenues and then profitability.

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

Mr. Fater: I appreciate your use of the term "long-term investor." Clearly we are a great value play. While every CEO believes his stock price is cheap, I'm going to be a more realistic CEO: Our stock price is what it is. As an entry point to getting into our stock, it's a great value. All an investor needs to do is consider all the applications and our revenue model. With just what we have today, we have the potential to touch 77 million patients annually in the United States alone on a recurring basis. That's a $3.9 billion market, without counting the international market or any future applications. So long term, which I'd say is probably a two- to five-year horizon, things will manifest themselves, and they'll start to do so over the rest of this year and into next year. Vicor is a great opportunity. It's just that a lot of people are not aware of the story, so they can't appreciate it.

TWST: Anything else you want to cover?

Mr. Fater: I don't think so. I've covered all of the points.

TWST: Thank you. (MJW)

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Vycor Medical, Inc. (VYCO.OB)

KENNETH T. COVIELLO brings to Vycor Medical, Inc., over 25 years' experience in building profitable medical device companies. His broad experience includes the successful design, development, sales, marketing and operations of various medical devices. Mr. Coviello's most recent position was at Misonix, Inc., a Nasdaq-listed medical device company that specializes in ultrasonic surgical devices for orthopedic, neurosurgical, wound care, laparoscopic and urological applications. Mr. Coviello served as the Senior Vice President of medical products, with responsibilities for sales, marketing and operations. Previously, Mr. Coviello served as President of Lumex and Vice President of Graham Field, both manufacturers of medical devices.

SECTOR – HEALTH SERVICES

(ALF603) TWST: Would you begin with a brief historical sketch of the company and a picture of things you're doing presently?

Mr. Coviello: Vycor was started in 2005. It was actually founded by Heather Vinas, and we set up a company to specialize in neurosurgery. In the early stages, it was research, development, prototyping, lining up manufacturers for production. In 2007 and early 2008, we concentrated on field testing of the prototypes and raising capital. In 2008 we took it all the way into production and launched the VBAS at the 2008 CNS show. We zeroed in on a product sector that really hasn't been changed in over 80 years, and that's brain retraction, with a very simple device that we feel offers next-generation features and represents a significant advancement of brain tissue retraction.

TWST: Have there been any new developments since we last spoke with Vycor's President, Heather Vinas, in April?

Mr. Coviello: We started registration to market in China. We applied for SFDA registration, the equivalent of the FDA. We received some questions and additional paperwork to fill out and replied. So we're still in the waiting mode on that, but we're hoping that that clears over the next four or six months so we can start marketing the product there. In addition to that, we have put on several more international distributors, and we hired an experienced sales director for the company. So we're continuing to increase our marketing efforts.

TWST: Ms. Vinas said much of the work was being done by the two of you, so that would be a big step.

Mr. Coviello: Yes, we did have our first white paper by the University of Illinois published in Surgical Technologies, and it is now available through PubMed.

TWST: Your ViewSite Brain Access System, or VBAS, has been on the market for about 18 months. How are things going?

Mr. Coviello: They are going well; 2009 was a difficult year for Vycor. We had difficulty in fundraising, like many companies did, after the stock market crash. At the end of 2009, the company was recapitalized and Fountainhead Capital became the majority shareholder. Since 2009 we've been really stepping up our marketing activities, so we have a lot more momentum going in the field. More hospitals have recognized the product and are requesting evaluations. We're adding to our distribution network, so we expect momentum to be building quarter by quarter.

As far as what VBAS does itself and what it's focused on, I mentioned its brain retraction. Up till the time we introduced VBAS, the instruments that were being used were called blade or ribbon retractors. To visualize it, they almost looked like small malleable nail files that the physician uses with a head frame, and then they separate the tissue as they go in deep into the brain. These ribbon retractors hold back the tissue to allow the surgeons to start working in the brain on their surgical target, whether it's a tumor or a hematoma. There are published articles about brain retraction injury using these types of ribbon or blade retractors. They can create high venous pressure, which could lead to tissue damage. With Vycor's unique product line, we increased the surface area; they are elliptical shaped, so there are no edges to the retractor. We have a specially designed introducer, so as the surgeon is gently inserting the device into the brain to get to his target, this bullet-nose shape gently separates tissue with minimum tissue trauma. The benefit is a less-invasive method of getting deep into the brain. We also use optically clear plastic to enable the surgeon to see what's happening in the surrounding tissue. With traditional metallic retractors, you don't always see the tissue behind the retractor, perhaps bleeding or perhaps tissue discoloration, which may mean tissue trauma. Common practice is to reposition standard retractors. With VBAS we are hearing it requires less repositioning, saves time, and it allows the surgeon to use less of certain common supplies, such as cottonoids or multiple retractors.

Initial feedback from surgeons has been speedier surgery times, requiring less setup, less repositioning and noticeably less tissue trauma. One of our major milestones is to collect data and document this. If we can scientifically document and publish the data showing that you could go deep in the brain and cause less

trauma, that can be significant. We believe it will show better patient outcomes. If this is documented in a peer review journal, that will be a major milestone for the product.

"The competitive advantages — our product is unique. It doesn't require a new surgical technique, so that means our learning curve is very short. We've been very fortunate in that we're able to show surgeons the product, they understand the concept, and they're fairly confident with using it even on their first case because it's so intuitive of how to use it."

TWST: Tell us a little bit about your own background.

Mr. Coviello: I've been involved in health care my entire career. I started in a cosmetic and drug company in marketing. Then I moved to a medical equipment company. I was there for 19 years, starting in marketing and becoming President of the company; it was Lumex/Cybex. I did a short entrepreneurial business of my own down in Florida and then went back into the health care product field at Graham Field. I was Senior Vice President. Graham Field generated revenues of about $300 million. I then went into surgical devices with Misonix as Vice President of business development, and I became Senior Vice President at Misonix. Misonix concentrated on therapeutic ultrasound devices for surgery. With Vycor and VBAS, and I couldn't pass up one more shot at owning a company with my partner.

TWST: What is the competitive landscape like for you? What do you see as your competitive advantages?

Mr. Coviello: The competitive advantages — our product is unique. It doesn't require a new surgical technique, so that means our learning curve is very short. We've been very fortunate in that we're able to show surgeons the product, they understand the concept, and they're fairly confident with using it even on their first case because it's so intuitive of how to use it. We compete with ribbon or blade retractors, but ribbon and blade retractors use head frames, and we're compatible with head frames. So in a way, we're a complementary product, and the only thing we really compete on is the technology that's been there for 80 years, which we think Vycor has significant advantages over. It's a disposable product, has a list price of $695, so we don't have to go through the capital product committees.

TWST: When we spoke with Ms. Vinas, Fountainhead Capital owned an 85% share of the company. Have there been any changes there? Ms. Vinas mentioned that making more shares available to other investors was a goal.

Mr. Coviello: Yes, we did raise additional capital. I don't know if it was just before or just after Heather's interview. There was a round for about $750,000 that we issued shares for, and we recently issued more shares under a private placement. There were 675 million shares outstanding as of June 30.

TWST: You mentioned 2009 was a difficult year, and you completed a recapitalization in February. Do you feel the company has really turned the corner from last year?

Mr. Coviello: Yes, when you're a small, single-product company, and with the economic conditions that existed, I think the fact that the company survived is an endorsement that it has a good product and good technology. Fountainhead Capital did step up; they took over majority control of the company, but they have secured funding for the company and put money into the marketing and sales activities. So I think that with the groundwork that's laid, it should propel Vycor forward.

TWST: What have you been doing to ramp up marketing and sales? What are your future goals?

Mr. Coviello: A major hurdle that any company faces now in hospitals is getting through the product committee. Hospitals — and I'm sure you hear this from other medical device companies — are getting tougher and tougher on new products. We've aligned ourselves with several leading surgeons and hospitals that we can refer surgeons to ask surgical tips on how to use VBAS and what the results have been. We work with only experienced independent reps that have existing relationships with neurosurgeons. We do have consignment programs now to help get into hospitals easier. A lot of hospitals are resisting multiple sizes and stocking a lot of SKUs, so consignment is one of our key marketing tools. We continue to have a liberal policy of helping the surgeon to evaluate the products easily by providing evaluations. Our first clinical paper has been published; we expect another one out before the end of the year, and that will help establish more creditability for the product.

TWST: You mentioned your efforts in China; you've been involved in several European and Asian markets. How does the business break down by country or region, and where are you targeting growth as you look ahead?

Mr. Coviello: We don't publish the breakdown by country, but international sales were about 25% of revenues. We have European distributors — Greece, Italy, Spain, Benelux, Sweden — we hope to be into the U.K. in the near future. China is where we're just waiting for marketing approval, and then we'll look towards registration in Japan and Russia.

TWST: Is the U.S. the largest market for you?

Mr. Coviello: The need is certainly global. The U.S. holds the best and the largest market potential for us, so we're focusing our efforts in the U.S. but have been fortunate to find good international distributors and partners willing to market the product and do the missionary work that's required.

TWST: Does the company give a great deal of attention to investor relations? Do you feel like you've given people, especially with these new shares, a good sense of what you have going on?

Mr. Coviello: That's going to be stepped up significantly in the near future. That's one of the roles of Fountainhead Capital for us. Not only are they a majority shareholder, they do have a consulting agreement with the company; they're experienced in investment banking and creating value for shareholders. So one of their main assignments is to create more public awareness about the company.

TWST: Looking ahead, you've said you're hoping to see things take off pretty soon. What are some year-by-year milestones or indicators that investors should look for?

Mr. Coviello: Certainly the sales number. The second and a very important indication would be the number of hospitals we're adding, as well as those signing up for evaluations. The selling cycle on a new product to get through a product committee today could take anywhere from 60 days to a year to get through. So there's a lot of activity that is taking place that may not show up in sales for six months or longer, but it's important that that groundwork is going on as we speak. That's certainly something that should be looked at as we go forward. Another is more global expansion distribution agreements and publication of more papers, along with the collection of data to prove that we accomplished what we said we did in the design parameters. As we get more clinical papers produced, that's going to increase adoption at the hospitals.

TWST: Ms. Vinas had some December 2009 figures: Over 50 U.S. hospitals had approved the product and purchased it, and about another 100 were going through the approval process or were in the evaluation process. Do you have an update on those numbers?

Mr. Coviello: We have an estimate of approximately 80 hospitals either purchasing or evaluating the product.

TWST: Ms. Vinas also made references to some potential new products hitting the market. Would you tell us any more about those efforts?

Mr. Coviello: We have an accessory planned for the VBAS line; it's actually an adaptor arm to ensure a more universal fit with the head frames. It will also help VBAS to be able to be integrated with image-guided surgery. After that we've had a prototype for anterior cervical retraction, which we think is actually a bigger market than brain, and development on that is pending additional fundraising. The company, and through Fountainhead Capital, is actively looking for acquisitions.

TWST: Anything happening on that front?

Mr. Coviello: Just searching, nothing to announce yet.

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

Mr. Coviello: One is that we have unique products. Vycor has been able to commercialize a very innovative product with relatively little money compared to some of the other R&D efforts that are going on by other companies. We've also cleared the regulatory path. We have 510(k) clearance on both the brain and the cervical access unit, and that's a major advantage and milestone because some companies spend millions and millions achieving that. We are in the revenue-producing stage with VBAS.

Another big reason, I think, is our technology is relatively simple, but it solves a rather serious and complicated issue for the surgeon. I think that's what's beautiful about Vycor and the business model. We have designed a simple, two-part plastic instrument that is involved in $150,000 procedure for the hospital. It doesn't take a lot of training or new surgical techniques to put this product to use right away. So unlike many other good high-tech companies that require a tremendous amount of education, training, on-site training, we think we've developed a unique product that can be put to use rather quickly and generate volume. The fact that it's disposable means that as we increase market share and acceptance, the sales numbers should go up geometrically.

TWST: Is there anything else you'd like to add? Anything else people should know about the company?

Mr. Coviello: We are focused on innovative products. We're not looking for commodity products. Our mandates are that the product has to deliver better patient outcome and contribute to overall lower health care costs because I really think that's the mark of a product in this environment. If you can't do those two things, you're going to eventually have problems.

TWST: Would you give me a sense of the type of opportunities you might be searching for?

Mr. Coviello: We're looking for products that have IP protection that either have 510(k) clearance or shortly to have regulatory approval. And the investment ranges that Fountainhead has put out is anywhere from several hundred thousand to $10 million-plus.

TWST: Thank you. (MJW)

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