

January 25, 2010

THE WALL STREET TRANSCRIPT

Connecting Market Leaders with Investors

The following report is produced by
THE WALL STREET TRANSCRIPT

01-25-2010

MEDICAL RESEARCH, DIAGNOSTIC SUBSTANCES, LIFE SCIENCE TOOLS REPORT

NOTICE

The Wall Street Transcript does not in any way endorse or guarantee the accuracy or reliability of any of the information, statements or opinions expressed in the reports or comments of other firms or individuals. We take due care to report or transcribe accurately what has been written or said by others but because of the possibility of human or mechanical error, we cannot assume any liability for the correctness of the transcription. We point out further that, of course, all opinions expressed are subject to change without notice. Neither the information or any opinion which may be expressed constitutes a solicitation for the purchase or sale of any securities referred to herein. For further information, contact the individual or investment organization concerned.

CHIEF EXECUTIVE OFFICER FORUMS/INTERVIEWS

Important Note: Wall Street Transcript forums and interviews with Chief Executive Officers are published verbatim as editorial content and include "forward-looking statements" (as such term is defined in the United States Private Securities Litigation Reform Act of 1995). These "forward-looking statements" may be subject to and be made pursuant to the "safe-harbor" provisions of Section 27A of the United States Securities Act of 1933, as amended, and Section 21E of the United States Securities Exchange Act of 1934, as amended. Since these statements are based on factors that involve risks and

uncertainties, actual results may differ materially from those expressed or implied by such "forward-looking statements". Such factors are often included in the company's filings of reports with the United States Securities and Exchange Commission, including Forms 10-K, 10-Q, 8-K and Proxy Statements; the company's annual and interim reports to shareholders and similar documents. In carrying out our responsibilities to our readers and to the Chief Executive Officers selected for forums or interviews, we are required to offer, and we offer, each Chief Executive Officer an opportunity to back-up the interview and provide our readers and potential investors with specific financial data, including earnings statements, balance sheet statements and other material business and financial data, through the sponsored publication of such reports or highlights therefrom, with meaningful information.

Founded 1963

**Published by Wall Street Transcript Corporation
48 West 37th Street, 8th Floor, New York, NY 10018
Copyright 2009 Wall Street Transcript Corporation
All Rights Reserved**

2010 Trends in Medical Technology

JUNAID HUSAIN SOLEIL SECURITIES GROUP, INC.



JUNAID HUSAIN has been associated with Soleil Securities since March 2007. He covers the medical technology sector, leveraging over 14 years of experience in the health care industry. Previously, Mr. Husain was with Leerink Swann & Co., where he was Vice President/Research Analyst on the medical supplies and diagnostics team. In addition, he was a health care consultant at Constella Health Strategies and Decision Resources, providing advisory services to pharmaceutical and biotechnology companies. Mr. Husain

has an entrepreneurial background, having worked for startup companies in the genomics, biochemical manufacturing and medical device industries. He is less than a year away from completing his third master's degree in government at Harvard University.

SECTOR — DIAGNOSTIC SUBSTANCES

(AAZ813) **TWST:** Tell me about your coverage in the medical technology sector.

Mr. Husain: In terms of how my coverage universe breaks down, I cover a miscellany of different spaces. Medical technology is a pretty broad space, and within that space there are numerous buckets. I cover a number of these buckets, including diversified medical supplies. And within that bucket, you've got companies like **Hospira** (HSP), **Baxter** (BAX), **ICU Medical** (ICUI) and to some extent **Mindray Medical** (MR), which is a Chinese company. I also cover the capital equipment universe, including the radiation oncology triumvirate — **Varian Medical Systems** (VAR), **Accuray** (ARAY) and **TomoTherapy** (TOMO). I also cover **Intuitive Surgical** (ISRG) and then **Hologic** (HOLX). On the diagnostic side of the house, I cover companies like **Sequenom** (SQNM), **Bio-Rad Laboratories** (BIO) and micro-cap stock **SenoRx** (SENO). Within all of the different spaces, there is a lot of cross-talk. Within my capital equipment universe, for example, I've got companies that also play in the diagnostics space, like **Hologic**. Their bread-and-butter business for

years has been breast imaging, but they also have clinical diagnostics, which includes the Cytoc cervical cytology business as well as molecular diagnostics through their 2008 acquisition of **Third Wave**. Even **Mindray Medical**, which is a capital equipment company, has a big part of its business levered to clinical diagnostics, including in-vitro diagnostics and hematology. So net-net, a very diverse medical technology universe but with a lot of cross-talk between the different spaces, which makes things interesting from an investment perspective

TWST: What are companies in this space doing to survive and flourish with all that is going on in their universe?

Mr. Husain: Broadly speaking, 2009 was a very tough year for everyone. For capital equipment vendors, it was a very, very difficult year. Hospitals were getting kicked in the gut on a number of fronts. First, patient volume and quality was a big concern. Lower patient volumes, patients falling out of health care coverage and going onto COBRA benefits, and then COBRA beneficiaries coming out of COBRA qualification — these issues weighed down the providers. So for the first three or four months of the year, there was a lot of concern that low hospital

Highlights

Junaid Husain is cautiously optimistic that we will see a rebound in hospital spending going into 2010. He also predicts medical supply companies will have a positive 2010, as hospitals begin to restock inventories. In this interview, Mr. Husain gives his top stock picks in both subgroups as well as his thoughts on upcoming health care reform.

Companies include: Hospira (HSP); Baxter International (BAX); ICU Medical (ICUI); Mindray Medical International Limited (MR); Varian Medical Systems (VAR); Accuray (ARAY); TomoTherapy Inc. (TOMO); Intuitive Surgical, (ISRG); Hologic (HOLX); Sequenom (SQNM); Bio-Rad Laboratories (BIO); SenoRx (SENO) and Abbott Laboratories (ABT).

patient volumes and/or poor quality of patients, i.e., indigent care, high-bad debt care, would weigh down the financial state at hospitals. Secondly, health care reform also created a lot of angst. With hospitals on the hook for roughly \$155 billion in savings over 10 years, reimbursement and cost pressures were — and probably still are — a major theme that we could see play out at hospitals in 2010 and beyond. And finally, hospitals were feeling completely bent out of shape in 2009 from a capital budgeting perspective, which made it difficult for them to make key investments. They fund capital expenditure in a couple of ways: They tap into their investment portfolios, or they use philanthropic donations, or they fund using their operating budgets. On all three fronts, hospital were feeling the pinch. Bottom line, the challenging hospital environment has had a trickle-down impact to this very hospital, a lot of my companies under coverage, including the capital equipment vendors, and even to some extent the diversified medical suppliers and the diagnostic manufacturers as well.

As I look to 2010, I'm feeling cautiously optimistic that we're going to see a rebound in the spending environment at hospitals. I do believe that capital expenditures for hospitals will start to creep back up. When I talk to hospital administrators, my sense is that they are starting to open up the purse strings. However, this spending is very selective and it's happening at only the best hospitals — the ones that are in the best financial situation, those hospitals that are able to take advantage of the challenges that competitor hospitals face down the street. What are these "have" hospitals doing? They're making the decisions needed to stay competitive and drive patient market share. How do they do this? Well, you invest in new technologies. When I look at the technologies that hospitals could potentially be investing in the New Year, I think radiation oncology is going to be an area that many hospitals look at very closely. Remember, radiation oncology is a big-bucks revenue generator for a hospital — it's one of the last great profit centers for hospitals. If you can drop \$2.5 million to \$3 million in radiation oncology box, the payback for that instrument can be anywhere from 12 to 24 months, depending on what kind of cancer census you have at the hospital. I think we'll start to see hospitals making those investments again in 2010. Certainly as the year-over-year comps get better, we could see hospitals back at the buying table for big-ticket radiation oncology.

I also follow the robotic surgery market though my coverage of **Intuitive Surgical**, which is a hold-rated stock in my universe. **Intuitive Surgical** has been one of those companies that has surprised a lot of us in the sense that they've been able to beat expectations quarter-over-quarter in a very tough market — not only a tough capital equipment market, but also a tough financing market for big-ticket items. I have consistently been the high man on the Street on my estimates for **Intuitive** on all fronts — on revs, on earnings, on box placements. Nevertheless, they consistently beat my expectations. It's interesting, the fact that they can beat my

very robust estimates for box placements quarter after quarter is a surprise. To me, it tells me that there are hospitals out there that are looking at the market very opportunistically. In my mind it means that hospitals are saying to themselves, "An investment in **Intuitive Surgical's** da Vinci robot is a way for us to win patient market share." The best hospitals are the ones that can see technology as an enabler of their business and revenue plans. By introducing technologies, hospitals can be on the innovation cusp, a fantastic way for hospitals to drive patients census. Lets be clear though, it's

not all across the board. Not all hospitals are purchasing these differentiated products; it's the "have" hospitals, not the "have-not" hospitals. The fact that the "have" hospitals are able to do this in a very tough financing environment makes me think that the runway for **Intuitive Surgical** and its box placements is still fairly long. Now valuation is a different story, and a lot of investors look at the valuation of **Intuitive Surgical** at roughly 40 to 45 times forward numbers and think that's a

stretch. That's a stretch even in the good times, let alone the bad times. So from a valuation perspective, I'm still nervous about the stock, and that's why I have a hold rating.

"The diversified medical suppliers had a better go at it in 2009 and could see a rosier 2010. These are companies like Baxter, Hospira and ICU Medical. These companies have bounced back a lot more quickly mostly because the patient volumes started to creep upwards as we got into the mid-point of the year."

1-Year Daily Chart of Hospira, Inc.

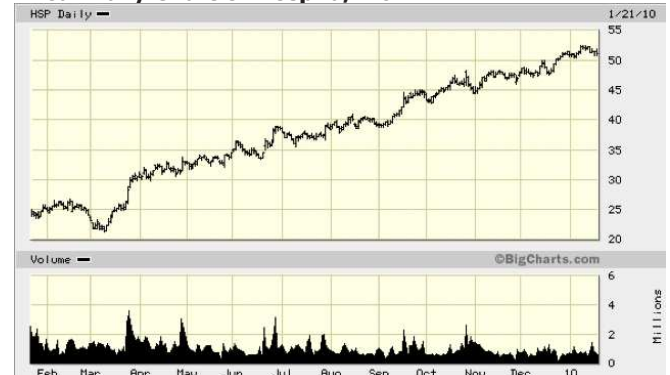


Chart provided by www.BigCharts.com

TWST: Is there any sector or subsector emerging from the economic difficulties more quickly than others?

Mr. Husain: I think that the diversified medical suppliers had a better go at it in 2009 and could see a rosier 2010. These are companies like **Baxter, Hospira** and **ICU Medical**. These companies have bounced back a lot more quickly, mostly because the patient volumes started to creep upwards as we got into the mid-point of the year. With the swine flu impact over the summer time, we saw a big trickle-down impact with more patients coming to hospitals. The hospitals, in anticipation of a tough flu season, started buying up products. Inventories were already light to begin with for the past year or year and a half. So again, hospitals adjusted accordingly, buying products they could not do without — connectors, tubing, antibacterials, gloves, gowns, etc. — so a

reasonable buying binge in the third and possibly fourth quarter for a lot of must-need consumables that hospitals absolutely must have in their supply rooms.

TWST: Who else do you like and why?

Mr. Husain: Following on that diversified medical supplies as an investible theme, I'm a big fan of **Hospira**. It is a buy-rated stock in my universe. I like **Hospira** for a bunch of reasons. I like **Hospira** because when I look at their businesses, they're playing in markets that are reasonably attractive. I've followed **Hospira** now for almost six years since they spun out of **Abbott** (ABT) back in 2004. Early in 2009, **Hospira** informed the Street that they were initiating a restructuring campaign, the so-called "Project Fuel." They're doing what you're supposed to do when you are in the midst of a recession. They're cleaning up their businesses, shutting down manufacturing facilities, laying off superfluous staff. Essentially, they're looking to become lean and mean. And ultimately, these efficiency improvements are very impactful to the numbers. For **Hospira**, it doesn't take much to move the earnings needle. If you improve your gross margins by a 100 basis points, you can improve earnings by anywhere from \$0.08 to \$0.10. They had a lot of benefits off of Project Fuel. Now cost savings are a one-time mission. Beyond cost savings, companies have to do something real on the revenue line. On the revenue line, **Hospira** was bolstered this year by the fact that they launched this drug, it's called oxaliplatin. Oxaliplatin is a cancer drug, which they launched at risk with patent litigation pending from the innovator pharmaceutical company. Despite the at-risk launch, they were able to successfully launch the drug, which enabled them to be one of first imitators to the market. Clearly this product has helped their numbers. Heading into their analyst meeting in September of last year, I was thinking that they would raise expectations for the year, which they indeed did. From there, it's been a steady up into the right for them as they look to diversify their drug business. The one thing that I like about **Hospira** is that they are starting to move away from their stodgy, boring diversified medical supplier history, and take on an almost edgier look and feel. They recently announced they are going to make the acquisition of certain generic specialty injectable assets from an Indian manufacturer, a company called **Orchid**. This is going to bring in anti-infective products, which they didn't have before. These investments in portfolio products, like specialty injectables, could improve the overall business — improve the pipeline, drive sales, improve margins and ultimately drive earnings power. So I like **Hospira** a lot.

TWST: Anybody else?

Mr. Husain: Part and parcel to **Hospira** is **ICU Medical**. It's a small-cap stock in my universe. I like **ICU Medical** for a number of reasons. **Hospira** and **ICU Medical** are joined at the hip. Roughly 40% to 45% of **ICU Medical**'s revenues flow through **Hospira**'s distribution channels. So when **Hospira** is doing well, **ICU Medical** is doing well. **Hospira** sells these infusion pumps.

You'll find infusion pumps at hospitals. If you've got a 500-patient hospital, then there's a good chance that this hospital has 500 infusion pumps. It's an important part of **Hospira**'s business, and it's a very important part of **ICU Medical**'s business because any time **Hospira** sells an infusion pump contract, they also sell a contract for **ICU Medical** products. **ICU Medical** sells these connectors, and they also sell IV tubing. Pretty boring and unsexy

business, but products that you can't disintermediate from the health care system. **ICU Medical**'s products are must-need for hospitals and their pumps. So when **Hospira** sells an infusion pump contract, it also sells a contract for these must-need consumables. What do we know about **Hospira**'s infusion pump business? Their infusion pump business is in the midst of an upgrade cycle to its latest and greatest infusion pump called the Symbiq. As they roll out the Symbiq infusion pump,

they're going to be rolling out contracts for **ICU Medical** products. **ICU Medical** is also in the process of rolling out new products of its own in the oncology space, and I like these oncology products because they are high-margin products with better-than-corporate-average margin. These products are basically differentiated consumables that are used to assist in the transfer of chemotherapeutic agents from vial to a patient and prevent aerosolization of the cancer drug upon administration to a patient. These little connectors that costs anywhere from \$5 to \$10 have turned it into a very nice business for **ICU Medical**. In 2008 they made \$12 million on this business alone, and they could potentially do anywhere from \$15 million to \$17 million in 2009 full-year. The **ICU Medical** story is an eloquent business model: Take these almost commoditized-type products, add some smart thinking, add some engineering, add some marketing and you've got a win of a product. And ultimately, you've got a hospital customer for life.

"As I look to 2010, I'm feeling cautiously optimistic that we're going to see a rebound in the spending environment at hospitals. I do believe that capital expenditures for hospitals will start to creep back up."

1-Year Daily Chart of ICU Medical, Inc.

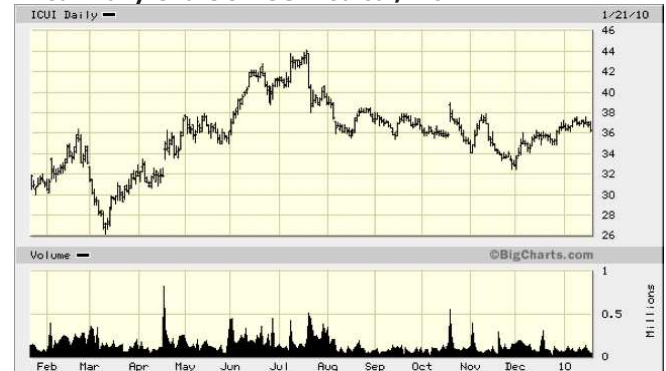


Chart provided by www.BigCharts.com

TWST: Will we see big changes in the sector with the health care reform situation?

Mr. Husain: I guess it remains to be seen. The biggest

angst that we're hearing from the medical technology industry in general has been on the device tax. Everyone is assuming that the device tax is going to be somewhere between 1% and 2%, maybe more, maybe less. So depending on what iteration of health care reform is eventually signed into legislation — and that seems to be a rolling target these days — the device companies could potentially be on the hook for about anywhere from \$20 billion to \$30 billion over 10 years. Will they take out the device tax? I've talked to a bunch of lobbyists on Capitol Hill and the signal-to-noise ratio tells me that it's looking like a fait accompli. The device tax could ultimately be implemented. Again, health care reform is a moving target these days, especially after the events in the Massachusetts senatorial election. So it remains to be seen. Should some form of device tax ultimately be implemented, I'm skeptical about its longer-term impact. I've talked to hospitals that tell me that they view the device tax as kind of a tax on the hospitals themselves because they potentially see the manufacturers raising their prices in order to compensate for a device tax that the manufacturers are not cool with. Nevertheless, there are arguments to be made on health care reform being beneficial to the medical technology industry. If we really are going to be adding millions of insured patients into the health care system, presumably these patients will need to go to hospitals, and presumably these hospitals are going to need to buy equipment and consumables to serve these patients. So ultimately, this could potentially be a boon to all the medical technology vendors. Again, it remains to be seen. I'm hopeful of a trickle-down benefit over the next 10 years with health care reform, but we'll wait to see how the cards play out in Washington over the next few months. It should be interesting to watch.

TWST: Tell us about your background. How did you become a health analyst?

Mr. Husain: I have been in the health care business now for about 14 years. I am actually a scientist by training. I did my graduate work in neuroscience, of all things. I was a bench scientist for a number of years before I crossed the chasm, so to speak, and started doing industrial science at a genomics company, followed by business development stints in biochemical manufacturing and medical devices. After business school, I had to do the management consulting thing for a number of years, consulting to biotechnology and pharmaceutical companies. So I did consulting for a number of years before I got into equity research, covering medical technology companies. I can't say that I've seen everything, but I have certainly seen a lot.

TWST: Is there anything else you'd like to add?

Mr. Husain: We've talked about diversified medical supplies. One area that we haven't talked about is China. I cover

Mindray Medical. **Mindray Medical** trades as an American Depositary Receipt on the New York Stock Exchange. **Mindray** is an interesting company. They IPO'd back in 2006. 2009 has been an interesting year for them. I should give you a little bit of background of the company. So the company derives about 50% of its revenues in the People's Republic of China. The company is based in China; it's based in Shenzhen, which is just North of Hong Kong. So this is a tried-and-true Chinese medical technology company. They play in three different segments — in-vitro diagnostics, diversified medical supplies and medical imaging. 2009 has been an interesting year because back in March of 2009, the Chinese central government indicated its intent to make large investments in health care reforms. So they decided to allocate something to the tune of 850 billion renminbi to invest in Chinese health care infrastructure. Now that includes expanding and building hospitals, and they are building a ton of hospitals not only in the urban areas, but more importantly in the rural areas that have only nominal care. And then they are also improving patient access to health care providers and facilities. So these major investments in health care reform obviously have a trickle-down impact, and that trickle-down impact would benefit a lot of Chinese companies, including **Mindray**. I think that from a med-tech perspective, **Mindray** is either number one or number two in its markets in Mainland China. If you're a **Mindray** bull, which I am, then you see them benefiting from health care reform and you believe that health care reform will be meaningful to the numbers sooner versus later through government contracts. In mid-January, **Mindray** was at a health care investor conference on the West Coast, where they pre-announced better-than-expected preliminary fourth-quarter results. It looks to me as if they're guiding 2010 fairly conservatively. So when I look at the Chinese markets and what those government tenders could mean, I think we should see some upside surprise in 2010. I like **Mindray Medical** for investors who want to play the Chinese market and want to play Chinese health care reform.

TWST: Thank you. (LMR)

Note: Opinions and recommendations are as of 01/15/10.

JUNAID HUSAIN

Analyst

Soleil Securities Group, Inc.

360 Madison Avenue

3rd Floor

New York, NY 10017

(212) 632-5300

www.soleilgroup.com

An In-Depth Look At Diagnostics

DR. ASHIM ANAND NATIXIS BLEICHROEDER, LLC

DR. ASHIM ANAND, Ph.D., is a diagnostics Analyst at Natixis Bleichroeder who exclusively focuses on this sector. He has worked in biotechnology and medical devices equity research both on the buy side and the sell side. Dr. Anand's medical background includes a stint as a scientist at Harvard Medical School, an entrepreneur endeavor (the founding of a private biotech firm), several consulting projects with large pharmaceutical companies, sales experience at Ranbaxy Pharmaceuticals and several peer-reviewed papers published in biomedical journals. He received an MBA in finance and accounting from Columbia Business School, a Ph.D. in molecular biology and biochemistry from UMDNJ/Rutgers. He also has a master's degree in biotechnology and a bachelor's degree in pharmacy from Sagar University.

SECTOR — MEDICAL LABORATORIES & RESEARCH (AAZ812) TWST: What do you cover within the medical services sector?

Dr. Anand: Officially I still cover medical devices stocks, but I focus on diagnostics. I focus on diagnostics per se without the categorization that sell side has done — life science tools stocks, medical devices stocks, biotechnology stocks or services stocks.

TWST: It's a diverse group.

Dr. Anand: Diagnostics is a diverse group. But from the perspective of health care, and from the perspective of a patient and also from the perspective of regulators, diagnostics is something that happens before treatment or something that governs the direction of the treatment. From that perspective, it is unified. And companies that are involved in diagnostics are what I focus on. The whole thesis on the sector essentially is that there is a sea change in the thought process, at least from the regulator's end, that they are increasingly seeing diagnostics as a way to reduce health care costs. From that perspective, they don't care about technology or the way the Street thinks. That increasingly would be the going theme.

TWST: Is the sector doing well?

Dr. Anand: Actually, it's doing better than almost all the health care sectors, including medical device, biotechnology, pharmaceutical sectors. As a whole, it's a mixed bag still. The challenge on the buy side and sell side is that though people are fairly comfortable in talking about a low-tech, medical device, like

diagnostic name. But then if you discuss companies with complex technologies, they will become increasingly uncomfortable. Essentially what that does is limit the preview of an investor. It's like the chicken-and-egg situation because a buy-side guy can't pick up the phone and talk about any diagnostics name/issue with a sell-side guy; sell-side guys are not motivated to cover this as a sector. If it's sort of like medical device, you call that person, and if it's a biotech, like, you call that person. So in the end, the diagnostics sector remains fragmented among medical devices, services, biotech and life sciences tools. That is the cycle — the vicious cycle.

TWST: Are we seeing a move toward molecular diagnostics within this area?

Dr. Anand: With the sequencing of the human genome, molecular biology is becoming a more and more integral part of medical education. It's a secular trend that we are moving towards molecular diagnostics. That rationally makes sense because if you think about an organism, you go to a doctor, doctor takes your heartbeat and all that, that's something at the organism level. Then he wants to go beyond that — he takes your blood sample,

or he sends you to an imaging lab. So that's another level. Then beyond that, if they are thinking there is something going on, then they take your tissue and it's sent to a histologist, so that's further down. Finally, further down is the molecular level. What I am saying is that whatever is manifested in an organism has a molecular basis. That was a debate 10 years ago. It's no longer a debate,

Highlights

Dr. Ashim Anand offer and in-depth overview of the diagnostics segment of the health services industry, detailing the specific trends, challenges and top stock picks that investors should be aware of when looking at this subgroup. He pays special attention to molecular diagnostics, which he predicts will become a more integral part of medical education and pre-treatment of patients.

Companies include: Quest Diagnostics (DGX); Genomic Health (GHDX); Myriad Genetics (MYGN); Inverness Medical Innovations (IMA); Quidel (QDEL); Celera (CRA) and Gen-Probe (GPRO)

everybody agrees about that. The question is whether or not we understand it at the molecular level. Physical manifestations of different things in health and disease have a molecular basis, and more and more physicians understand the molecular level because they have been taught in medical school. That was not the case before. There is a secular trend towards molecular. Now having said that, the problem is that molecular is complex and physicians are typically not scientists. Typically they are more like, "Hey, let's just fix it fast. I have to learn so many diseases, I have to do so many things, including billing, etc., and now you want me to do a diagnostics test?." Generally that is the thought process of a physician. I don't blame them — they have to learn a lot of things. It's one thing that they are being taught molecular biology, but they are not like, "Hey, we got to really be up with it and apply it."

Second is that doing things at the molecular level needs more expertise in terms of a technician who is doing it because they need to be trained well in molecular biology, both the understanding of it and doing it practically in labs. The availability of these technicians is scarce and development is expensive. Even in this economy, where unemployment is like 10%, there is a huge shortage of technicians who could actually do molecular stuff. Third, the instrumentation that is needed for that is also expensive versus the legacy instruments, which we used for non-molecular stuff. Of the different types of labs, we have only a small proportion of the reference labs — all sorts of labs where actually a physician sends our blood for analysis — are actually molecular. The capital-intensive part and the labor part becomes a deterrent in terms of labs' eagerness to adopt molecular diagnostics.

Fourth, from the test point of view, the deterrent is that most of the molecular tests have to be FDA approved. There is a service model where you do it in-house and you don't have to get FDA approval. FDA approval forces a manufacturer to go through the same process as a biotech or a pharmaceutical company has to go in terms of approval. In comparison to drug approval, a diagnostics approval is much less cost intensive, but it's not like a walk in the park. These deterrents have slowed the secular trend that makes sense in terms of going from the protein based or non-molecular to molecular.

TWST: What other trend are we seeing out there?

Dr. Anand: So let's start with maybe the broad-based trends in molecular. The first one I would point to is health care reform related. I will point out three bullet points here. First is a lot of companies in diagnostics are like service companies, like **Quest (DGX)**, and then there are companies like **Genomic Health (GHDX)**, **Myriad Genetics (MYGN)** and all — they don't go through FDA. They have the service model, in which you send your sample over there, and they perform the diagnostics test and analyze results for you, the physician. And they've been approved to do that. There is going to be some reimbursement reduction by Medicare Part B, about 2% starting this year. It's not a big deal, but the trend is worrisome because over last 25 years, every year there has been

an incremental increase. There is going to be a 2% decrease and essentially the Obama administration wants to use that savings in terms of giving health insurance to everybody. The second is if health care reform goes through, there would be more volume of diagnostic tests. So just simple math. They say about 50 million people or so are uninsured.

If they come on board, then essentially right now 250 million people who are insured. You add another 50 million to those, so essentially it's a market expansion. There would be more volume of diagnostic tests, which will benefit the whole industry. That's the point number two. The third is with the Obama administration thinking of ways to contain costs, they

are thinking of having people pay a copay whenever a diagnostic test is done. That would be a negative. But overall it's positive because a 50 million-person increase in market size would take care of these other two negatives, which are just incremental negatives.

"The whole thesis on the sector essentially is that there is a sea change in the thought process, at least from the regulator's end, that they are increasingly seeing diagnostics as a way to reduce health care costs. From that perspective, they don't care about technology or the way the Street thinks. That increasingly would be the going theme."

1-Year Daily Chart of Genomic Health, Inc.



Chart provided by www.BigCharts.com

So one trend was health care reform related, the other is macro economy related. There are three points again here. Related to the macro economy, the first downside is that people who are losing jobs are losing health insurance too. There is COBRA, but that's essentially a buffer time, it's not forever. If you lose your health insurance, then you are not going to doctors unless you really, really have to. And you are not going to go there and get your diagnostic test done unless you think you are in like really serious condition. That is a negative for the whole industry. The second point is kind of geography dependent — the people who actually haven't lost jobs, and they live in Midwest or other relatively less economically well-to-do regions of the U.S., would like to defer a diagnostic test. Typically on the East and West Coasts or the other relatively richer areas in the United States, this won't be true. But in the Heartland, if you will, some of the tests, for example, that have a copay of over \$50, people will think twice before going for

a test. In those areas, no doctors will say you should get them. They'll think, "It's not that I am dying of this right now, right? It's not medicine, it's a test, which will probably point to something. And maybe I can actually wait six months to actually become more economically viable and then do it." So some of the people in the Heartland are deferring these tests. That's another macro economy-related negative.

Then it's again macro economy related, but sort of indirect. The customers of a diagnostic company — so it could be the distributors who actually go out there and sell these tests to physician office labs or hospitals, or it could be the hospitals per se who buy these tests directly or these instruments directly — they are having a money crunch, especially hospitals. Hospitals are going bankrupt and all that. Given the cash crunch, the customers of diagnostic companies are having a hard time putting capital spending into buying big instruments. For example, let's say if you were a lab who wanted to go molecular, philosophically you are all set. But then because of the money crunch you'll say, "Well, let me wait for a year." So that's on the instrument side. Then on the consumable side — most of these instruments need consumables — you would want to manage your inventory. You wouldn't want to, like, stack up on consumable. So both of these things actually negatively affect diagnostic companies.

"With the sequencing of the human genome, molecular biology is becoming a more and more integral part of medical education. It's a secular trend that we are moving towards molecular diagnostics."

within 15 minutes I know the answer that actually it's influenza. The other version of this test would be that you take your kid to the physician, and the physician says, "I don't know what it is. It could be one of those, but let me take a sample from your throat and send it to the lab, and then come back to me in 15 days. Then I'll know what it is." So that would be the central lab type of diagnostic test. The trend is increasingly towards point-of-care diagnostics, and the

idea behind that is that a point-of-care test might be expensive, but if you include the whole wastage of time to visits to the doctor and the fact that the infection could be very bad in 15 days, the overall costs to the health care system of the point-of-care tests are much lower. That's why there is a trend towards point-of-care. That's number two.

In terms of molecular diagnostics, the other thing that is working for molecular diagnostics, other than the fact that people actually

should go molecular, is that molecular diagnostics are getting into new markets, new markets both geographically and also in terms of tests. For example, maybe there wasn't a test for detecting recurrent risk of breast cancer before, but now there is. It's a market which was not touched upon by molecular diagnostics before and which is being touched now. It's that and the fact that molecular diagnostic companies are going out in Europe, and now they are starting to go in Asia to put down the infrastructure for increasing utilization of molecular diagnostics. Some of the economies are actually expanding even in this downturn. Brazil, China, India — those guys have money, they are starting to have money to do this. Finally, a short-term thing, but it really was a big deal last year, that is swine flu. Swine flu, my call has been that U.S. swine flu is over now, at least the strain that started in like June, July last year. But what swine flu has done is create a windfall for a lot of diagnostic companies at a time when generally you don't have any influenza revenues. Typically the seasonal flu is December to February. Around these three months, essentially they sell most of their tests. Essentially it's like a two-quarter thing; there is a benefit in the fourth quarter and then in the first quarter. But swine flu came at a time when the flu actually dies down. A lot of companies saw profit going through their bottom line because of this untimely and pretty aggressive swine flu. Now that's a one-time thing, but because of what happened, a lot of molecular diagnostic companies which were not in the swine flu or influenza area, they were focusing on other things, they suddenly got interested in it. And now they have got their tests together for swine flu. But then the swine flu has gone. But in the long run, if you think about it, it increased competition, it increased the number of different ways people are making diagnostic tests for swine flu. This can go beyond influenza testing into other indications. So overall, this windfall actually not only was good for some of the companies at least for the short time, but it kind of attracted other companies.

TWST: What company do you like right now within the sector and why?

1-Year Daily Chart of Myriad Genetics

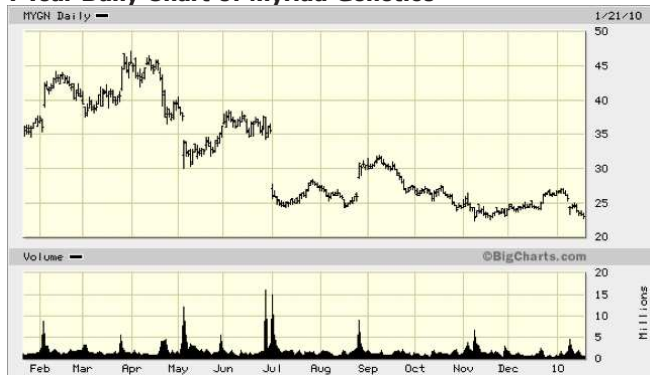


Chart provided by www.BigCharts.com

Then there are industry-specific trends, and of those trends, the most important trend is the secular trend in terms of health care cost savings that proper diagnostics can deliver. The second one is a move towards point-of-care diagnostics. Point-of-care means that diagnosis happens near to the patient or near where the treatment is being administered. The most basic example and the best example of that is the pregnancy test. You think that you might be pregnant, you go to a pharmacy and buy the test, and deliver the test yourself. Those tests are pretty accurate. Another example is you take your kid to the doctor suspecting influenza, it could be influenza or it could be strep throat. If a physician does a point-of-care test,

Dr. Anand: These secular trends have different meanings for different companies, and the companies that I will tell you that I like, that would have something to do with the secular trends. But it will also have to do a lot with what management is doing and what's their evaluation. So right now I have a buy rating on **Inverness (IMA)**, **Quidel (QDEL)**, **Celera (CRA)**, **Gen-Probe (GPRO)**, and **Myriad Genetics**. **Inverness** and **Quidel** are both point-of-care. Both of these companies benefit from that secular trend toward point-of-care diagnostics. IMA has done really well over last year. We initiated in November 2008, when it was a \$15 stock, now it's like \$44. But that has partly to do with the secular trend and partly to do with the fact that 2008 was extremely bad year for them. The Street had gotten very negative in terms of their acquisition strategy. However, now the company stands alone in terms of delivering, meeting or beating Street estimates consistently over 2009. Some of the objections that the Street had in terms of their strategy are moot now. **Inverness** could trade at a premium, but then it is an acquisitive company. A dilutive acquisition could be a challenge. **Quidel** is a well-understood company which gets outside benefit from influenza, and their gross margins move along with the amount of influenza sales they do. And lately there has been a lot of influenza sales. But this company generally trades at a premium to its peers. However, in the last two months or so, as investors started thinking that the benefit from swine flu is over, there was a big fall off. That made the stock extremely cheap in comparison to its peers, like 25% cheaper or something. The valuation has become attractive on this company, even though the swine flu has gone away. Recently they acquired a company, **Diagnostic HYBRIDS**, which would diversify their revenue base away from influenza to cater for the variability in influenza. So that's **Quidel**.

Celera had a tough year last year, but the last two months or so it has recovered beautifully. The challenge last year was that some of its services revenues, the third-party payers, were not paying up. So now that situation has been improving. The story with **Celera** is that it has a lot of intellectual property. This is the company, which sequenced the human genome, in fact actually they beat the national effort to sequence the human genome. They have a lot of intellectual property, and they are leveraging it in terms of developing new tests. And they are one of the leaders in the exciting field of personalized medicine. That essentially is sort of the story with **Celera**, they have like \$4 million or so in cash, no debt. It's sort of a value investment from that perspective; now it has recovered. But if they are able to deliver on improvements in terms of getting paid for the tests, then the stock will do even better, so that's why I still have a buy on them.

Then **Gen-Probe** is a leader in molecular diagnostics, which has two businesses related to molecular diagnostics, but one is essentially molecular diagnostics — they sell instruments and reagents to labs for doing molecular tests. Along with that they are involved in blood screening through a partnership with Novartis. The blood banking business had slowed down and there are a variety of reasons. Some of the reasons were actually related to

what we talked about in the macro economy, like the customers having cash problems so they are not buying instruments and not stocking up on reagents. That and the fact that **Gen-Probe** goes through Novartis in terms of selling the blood screening products.

Because Novartis is a big pharmaceutical company, blood screening is sort of a side business. So it doesn't move their needle too much if this business doesn't do too well. But then for **Gen-Probe**, it is a very important business, so that has led to pull back on the stock. But it's a blue-chip company, so a

lot of people have taken now the opportunity to buy it when the stock was cheap. And most importantly, **Gen-Probe** is getting into cancer molecular diagnostics. And that we believe is one of the most lucrative markets.

"The challenge on the buy side and sell side is that though people are fairly comfortable in talking about a low-tech, medical device, like diagnostic name. But then if you discuss companies with complex technologies, they will become increasingly uncomfortable."

1-Year Daily Chart of Celera Corp.

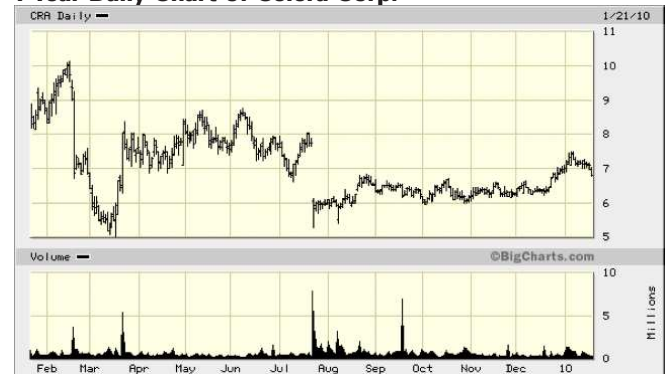


Chart provided by www.BigCharts.com

Then coming to **Myriad Genetics**, **Myriad Genetics** was one of those biotech-like diagnostic companies. Last year, they spun off **Myriad Pharmaceuticals**, with which the biotech part went away, and now they are 100% diagnostic company. They are a different animal in diagnostic companies in that their tests tell you about the risk of developing a disease. It tells that at the molecular level, the disease process could start. A disease at the molecular level could then filter through to the cellular level, and the physiological level and the body level. **Gen-Probe's** product could take your blood and tell look, yeah, you are developing this disease. The most famous test is the BRACAnalysis, and the company generates most of their revenues through BRACAnalysis. They have like eight or so more tests, but essentially what has happened with the stock is that essentially due to the macro economy and some of the points which we have already discussed — people losing jobs and people who have not lost jobs who are thinking, "I don't want to pay a \$50 or \$100 copay," they defer a test — those things have led to decrease in

the volume of BRACAnalysis tests. And that has led to **Myriad Genetics** actually not being able to deliver sequential revenue growth. That is what the Street has come to expect. Like, they still grow much faster than anybody else, but as you know, in the Wall Street community, if you are up sequentially every quarter for last five years, they take it as a rule that you would. And the day you don't, people are harsh on you, and they think the sky is falling. There are challenges, but still you have to see the yearly growth rate is still pretty good. So that essentially has made the stock extremely cheap, and suddenly **Myriad** finds itself as a stock which is not liked. But that doesn't change the fact that they are in the field of cancer, which, as I said before in terms of when I was talking about **Gen-Probe**, that cancer molecular diagnostics is one of the most attractive markets partly because we are losing the battle on cancer, and diagnostics can help in terms of actually catching the cancer young and probably reducing the costs of taking care of a person who actually catches cancer. The company's products are unique and their margins are extremely high — one of the highest in the whole health care industry, irrespective of biotech or pharma companies or med device companies. So that's why I have a buy on them too.

TWST: Tell us about your background.

Dr. Anand: I was a scientist at Harvard Medical School in my previous life; my field of expertise was obesity. I discovered the first lean gene and that was a landmark in medicine. I am sure you know of leptin, lean gene diametrically opposite of leptin. The lean gene discovery changed how we think about obesity and in terms of the pharmaceutical and biotech companies, the direction they went in terms of discovering obesity targets. It's making this point that if you want to understand obesity, yes, you can look for obesity genes, but you could also look at lean genes. Its like to understand how to make money, you can look at people who got rich, but you could also look at people who were rich and who got poor. So that was good. And then later on at Harvard, I worked on childhood obesity. But at some point you feel that in terms of your contribution to science that you pointed out to the community, that that is one way to go about it. And people are working on targets for that, it's just it's kind of out of your hands then, right. And also pointing out to the community that childhood obesity actually is a bigger concern than obesity per se. So I was finding that it's limited

what I can do now after that in biomedical research. And finance sort of interested me, and especially investments because of its conceptual perspective that investment obviously is generally associated with money. However, investment actually plays a role in all aspects of your life. I saw that, the importance of right investments during my Ph.D. I went to a cancer lab then when I was reading about things, I sort of made this choice and said to my boss that actually I want to do obesity. I know cancer is important but — and then obviously the idea wasn't taken very well at that point because it's risky. He didn't have expertise and all that. But investment at that time and at that stage in that indication was very productive for me. Yes, there were some challenges in terms of starting a new thing, but same things you can say about relationships. You get into relationships, when you get into relationships, you make investments. It's not thought of as strategically, but if you really in a very cold way, if you think about it, it is strategies — you want to kind of invest in one person, you want to invest in a couple of people and see what works out and then kind of what way you go after it. You just remain in a committed relationship, or you kind of actually get married. And then after that how do you keep up that investment? The things go sour if you don't keep on investing. So investing is a very broad concept, and obviously I didn't think about investing in this way when I was in biomedical research. But after business school or during business school, I started thinking and that is what excited me, and the general excitement of actually learning new things. So that has been my part.

TWST: Thank you. (LMR)

Note: Opinions and recommendations are as of 01/15/10.

DR. ASHIM ANAND

Analyst

Natixis Bleichroeder, LLC

1345 Avenue of the Americas

44th Floor

New York, NY 10105

(212) 698-3000

(212) 299-4444 — FAX

www.natxisblr.us/en/index.html

An Insider's Take on Clinical Labs

KEVIN ELLICH RBC CAPITAL MARKETS



KEVIN ELLICH is a Senior Research Analyst at RBC Capital Markets. With 10 years of experience, Mr. Ellich's universe encompasses the industries of dialysis, home health, diagnostic imaging, outpatient surgical centers, senior living and health care business services. Prior to joining RBC Capital Markets in 2006, Kevin worked at Minneapolis firm Miller Johnson. Earlier in his career, he worked on the buy side for three years at American Express (Riversource) before moving to the sell side at Wachovia Securities. He was also

a Principal and the health care sector Analyst for almost two years at hedge fund Aplos Advisors, where he generated 500 bps of alpha above the health care sector benchmark before the fund closed.

SECTOR — MEDICAL LABORATORIES & RESEARCH (AAZ807) TWST: You cover health care services. What falls under that umbrella?

Mr. Ellich: Health care services encompasses quite a bit within the health care continuum. There are traditional health care facility companies, such as hospitals and HMOs, and then there are alternative site providers. Medical device and pharma companies manufacture products or some sort of device, whereas health care service companies primarily provide a service to patients.

Just to give you an idea of what's included within health care services, there are hospitals, nursing homes, senior living facilities — like assisted living — clinical labs, ambulatory or outpatient surgery centers, dialysis companies, hospice and home health care, imaging services, managed care companies — like **UnitedHealth Group (UNH)** — institutional pharmacy, PBMs, distributors, behavioral health care, clinical research organizations, or CROs, and health care IT.

TWST: In general, how is the health care services sector doing?

Mr. Ellich: The sector is doing okay this year. Looking at the performance relative to the S&P, the majority of the companies in the services subgroup are

performing better than the S&P. Last year the stocks did pretty well, too. There was good performance from the health care services companies in 2009.

Highlights

Kevin Ellich offers a comprehensive overview of the health care services sector, highlighting clinical lab companies and home health care as the fastest-growing subsegments. He is also positive on dialysis providers, as these companies provide recession-proof treatments to patients who can't afford to hold off for a later date. Mr. Ellich explains the impact personalized medicine will have on this market.

Companies include: UnitedHealth Group (UNH); Quest Diagnostics (DGX); Laboratory Corp of America Holdings (LH); DaVita (DVA); Fresenius Medical Care (FMS); MEDNAX (MD); Amedisys (AMED); Providence Service (PRSC); Res-Care (RSCR).

TWST: Why did they do well last year?

Mr. Ellich: For a few reasons: We were in a recessionary environment; the market was down and investors tend to shift to more defensive sectors during rough times, especially those areas where you shouldn't see as much volatility and what some consider counter-cyclical or recession-proof. This wasn't necessarily the case last year, as we saw some weakness because of the economy. And that was primarily due to lower utilization of health care services that negatively impacted volumes. People were delaying and foregoing medical procedures — some were medically necessary, some were more elective in nature. But when you have a higher copay or deductible, and you're struggling to pay your mortgage, your auto loan and put food on the table, then you can't spend your next \$25 for a copay to go to the doctor.

The other reason health care stocks performed well in 2009 was health care reform was a bit of an overhang on the sector, and the group traded lower in the beginning of the year, like the overall market. As we moved throughout the

year and people realized we were not going to a single-payor system, then the stocks started to recover, especially subgroups that could see an incremental benefit from health care reform, such as the hospitals.

TWST: Will health care reform affect this sector?

Mr. Ellich: Yes, the bill will make changes to reimbursement rates. They're also trying to provide more coverage for people who don't have it now, and that includes those who are unemployed or don't have another form of health care insurance. There are also individuals who have jobs, and their employers offer them health care insurance and they decline it; they would be considered the "young invincibles," or people who want to take home more money in their paycheck. But the government is proposing an individual mandate saying that if you don't have insurance, you will pay an additional tax.

TWST: So will more people be coming to the facilities?

Mr. Ellich: Yes, it could be a nice windfall for health care service providers. There are two ways of looking at this in terms of more people utilizing health care services and going to the hospital. One, you have an increase in volume, and volume that has some sort of health insurance. And then two, it could reduce bad debt since some of these companies, like the hospitals and even lab companies, treat patients who don't have insurance. If someone comes into the emergency room of a hospital, they have to provide care for them.

1-Year Daily Chart of Quest Diagnostics, Inc.

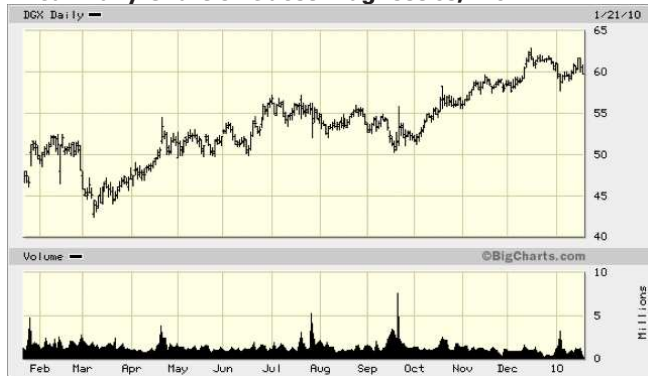


Chart provided by www.BigCharts.com

TWST: You talked about reimbursement under the new health care bill. Is that separate from Medicare and Medicaid CMS reimbursement policy?

Mr. Ellich: Correct. The way it works, there are two ways that reimbursement can be changed. One way is by Medicare, which is the Center for Medicare and Medicaid Services, as you alluded to, CMS. They update fee schedules every year that sets reimbursement rates. The other way reimbursement is changed is legislatively by the Congress. Health care reform will likely take precedence over the changes Medicare has made this year.

TWST: Within health care services, what are the fastest-growing areas?

Mr. Ellich: Within the coverage that I have, home health care is the fastest growing. Organic admission or volume growth in home health is roughly 10% to 15% long term. Home health providers have nurses and therapists that go into the home of the patients to provide skilled medical care versus having that patient in a hospital or a nursing home. Of the 19 companies I follow, I'd say the average top-line growth rate is roughly 10%. Clinical labs, like **Quest** (DGX) and **LabCorp** (LH), and the dialysis companies, like **DaVita** (DVA) and **Fresenius** (FMS), they grow top line 4% to 5% organically. I think **DaVita** can grow their top line closer to 6% to 7%. Other providers, like the imaging providers, home health companies, a company called **MEDNAX** (MD), their growth is derived by organic growth and acquisition growth. Because these companies generate good returns and they generate a lot

of cash flow, they use their discretionary capital to make accretive acquisitions and to increase their market share.

TWST: Are we going to see M&A activity in this health care field?

Mr. Ellich: We will. I think we'll see increased M&A activity.

TWST: Why?

Mr. Ellich: First, health care reform could hurt some of the smaller mom-and-pop providers. Let's use the home health industry as an example — there are only four publicly traded companies in that industry, and they have roughly 10% to 12% market share. Roughly 35% of the small providers are currently unprofitable. So if they're losing money now, they might lose more money once health care reform is done. Once everything is finalized, I expect the home health companies to go on a shopping spree. They might be able to buy these smaller home health agencies at cheaper valuations and increase their market share. That is part of the long-term growth strategy for the public companies. **Amedisys** (AMED), the largest company in the space, with a \$1.4 billion market cap, just presented at a conference today, and they indicated that they will be aggressive and very active on the acquisition front. Actually, all four of the companies have more or less stated more development and acquisitions is part of their strategy.

TWST: I know you recently downgraded Providence Service Corp. Why?

Mr. Ellich: **Providence** (PRSC) is in the government-sponsored social service business. They have case workers that go out and provide social services to clients in their homes — all of their revenues comes from government funding, whether that is federal, state or through local governments. Medicaid funding, which is partially state funded, has been under pressure over the last 12 to 18 months. For 2010 we believe the outlook isn't much better than it's been. Over the last 12 months, **Providence** has had a nice rebound off its lows from over a year ago, with the stock up over

"There are a few companies that I like right now, and I'm focusing on high-quality companies. I've been recommending companies like the lab companies Quest and LabCorp. They're stable, good business models."

1,000 percent. If you look at the chart going back two years, **Providence** went from \$26 per share to \$1, and now it's back to around \$16. And it is still relatively cheap, trading at around 10 times earnings. But I see limited upside from here. While there might be an increase in the number of clients or Medicaid beneficiaries due to health care reform, I think it could be challenging for states to balance additional funding with the services provided to incremental beneficiaries.

Another company that I follow, **Res-Care** (RSCR), which is another government-sponsored social services company, just announced that they are going to miss their 2009 guidance yesterday. The reasons for the guidance miss were similar to why I downgraded **Providence**.

TWST: Who do you like in the sector right now?

Mr. Ellich: There are a few companies that I like right now, and I'm focusing on high-quality companies. I've been recommending companies like the lab companies **Quest** and **LabCorp**. They're stable, good business models. They could see some benefit from health care reform if there are more people with health care insurance, even if it is Medicaid. This could increase testing volume for **Quest** and **LabCorp** since the overall testing market could increase, and these patients might not have been using health care services in the past. Both **Quest** and **LabCorp** generate tremendous free cash flow — free cash flow yields around 10%. For **Quest** that's almost \$1 billion that they can use to buy back stock; they can deleverage their balance sheet, or they can look for strategic acquisitions. And the long-term trends for the clinical lab testing business are good. We see more genetic or esoteric testing, and that is a higher-price, higher-margin business. And then a long-term opportunity for the lab companies is personalized medicine. That means finding the right treatment for the right person at the right time. The average blockbuster drug might only be effective on 50% of people, so why even waste money prescribing it to someone where it might not work versus doing a genetic test to determine if that drug will be effective or what the best treatment for that individual might be? While the test might cost more upfront, it should benefit our health care system and help lower costs over the long run.

Another group I like is the dialysis providers, **DaVita** and **Fresenius Medical Care**. Dialysis is one of those treatments that is recessionary-proof. People don't have a choice if they have kidney failure or end-stage renal disease. They either have to get a kidney transplant, or they have to get dialysis three times a week, otherwise they will die. Another interesting aspect of the dialysis industry is that Medicare provides health insurance coverage for everybody after 30 months, regardless of age. So it's not just for the old people, it could be a 17 year old who needs dialysis. And after 30 months' being on a primary insurance, Medicare will pick up coverage. That's the good news. The bad news is these companies indicate that they don't make any money on the Medicare patients because the rate is so low.

TWST: Should investors have money in the health care services sector right now?

Mr. Ellich: Sure. If you think about the long-term trends,

the American population is getting older and demographic trends bode well for the health care sector. Older people utilize more health care services than younger people. The lab industry is a great example. The average person over the age of 60, or the average senior citizen, gets lab work done about four to five times more than

someone who is 35. Another positive factor for the lab companies is lab test results influence about 70% of medical treatment decisions. Primary care physicians are typically trained to look for signs and symptoms when they see patients. But it's the lab test that verifies the physician's assessment and ultimately impacts the treatment options.

You cannot have a health care system without labs.

"The average blockbuster drug might only be effective on 50% of people, so why even waste money prescribing it to someone where it might not work versus doing a genetic test to determine if that drug will be effective or what the best treatment for that individual might be?"

1-Year Daily Chart of DaVita, Inc.

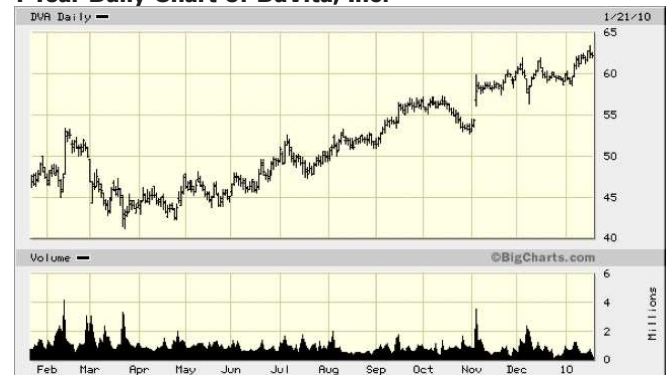


Chart provided by www.BigCharts.com

TWST: Tell us about your background. How did you become a health care services analyst?

Mr. Ellich: Very interesting story. I didn't come from the industry, meaning I didn't work within the health care field, unlike my wife Shonda, who is a registered nurse. I started by working for an analyst who followed the health care services industry at a different firm. I left that firm in 2004 to become a health care sector analyst at a hedge fund. Then I came back to the sell side, given my knowledge of health care services. When I was on the investment side, or the money management side, we invested a lot in health care services — not just the companies that I follow now, but we invested in the managed care companies, medical device companies, PBMs, the major distributors, CROs, major pharma, like **Pfizer** (PFE) and **Merck** (MRK), even **Amgen** (AMGN). We didn't invest in biotech since there are too many binary events. The hedge fund experience really opened my eyes and helped me understand how everything works together; it was a really good experience. Coincidentally, the analyst that I started my career in health care

services with at that other firm recently joined the health care team at RBC, a gentleman named Bill Bonello, who will follow a different subgroup of health care.

TWST: Is there anything you would like to add?

Mr. Ellich: One more company that I like, that had really good performance in 2009 is **MEDNAX**. It's a practice management company that focuses on physicians that deal with newborn infants in need of critical care. They have neonatologists that staff the neonatal intensive care units (NICUs) at hospitals. Approximately 11% to 12% of all live births are either pre-term or low birth weight, which leads to an admission into the neonatal intensive care unit at hospitals. These units are very specialized and are considered high cost, but these physicians are dealing with infants that could be one and half pounds and struggling to survive. But because the medicine and care for these infants has improved over time, these premature infants can develop properly and lead a normal life. The birth rate declined in 2008, which pressured shares of **MEDNAX**, and I believe it stabilized in 2009. If the birth rate starts to improve in 2010, this could provide a nice tailwind and help drive top-line and earnings growth for **MEDNAX**.

TWST: Thank you. (LMR)

Note: Opinions and recommendations are as of 01/14/10.

KEVIN ELLICH
Senior Research Analyst
RBC Capital Markets
60 South Sixth Street
Minneapolis, MN 55402
(612) 371-2711
www.rbccm.com

Disclosure:

Laboratory Corp. of America Holdgs, Inc.: Research personnel,

including the analyst or analyst team responsible for this report or recommendation or any individuals directly involved in the preparation of the report, including their supervisors, hold(s) or exercise(s) investment discretion over a long position in the common shares of Laboratory Corp. of America Holdgs, Inc..

Clariant, Inc.: A member company of RBC Capital Markets or one of its affiliates received compensation for investment banking services from Clariant, Inc. in the past 12 months.

RadNet, Inc.: RBC Capital Markets is currently providing RadNet, Inc. with non-securities services.

Amedisys, Inc.: RBC Capital Markets is currently providing Amedisys, Inc. with non-securities services.

Res-Care, Inc.: RBC Capital Markets is currently providing Res-Care, Inc. with non-securities services.

Providence Service Corporation: RBC Capital Markets is currently providing Providence Service Corporation with non-securities services.

Fresenius Medical Care AG & Col: RBC Capital Markets is currently providing Fresenius Medical Care AG & Col with non-securities services.

Clariant, Inc.: RBC Capital Markets has provided Clariant, Inc. with investment banking services in the past 12 months.

RadNet, Inc.: RBC Capital Markets has provided RadNet, Inc. with non-securities services in the past 12 months.

Amedisys, Inc.: RBC Capital Markets has provided Amedisys, Inc. with non-securities services in the past 12 months.

Res-Care, Inc.: RBC Capital Markets has provided Res-Care, Inc. with non-securities services in the past 12 months.

Providence Service Corporation: RBC Capital Markets has provided Providence Service Corporation with non-securities services in the past 12 months.

Fresenius Medical Care AG & Col: RBC Capital Markets has provided Fresenius Medical Care AG & Col with non-securities services in the past 12 months.

Blurred Lines Between Life Sciences & Diagnostics

STEPHEN D. SIMPSON

NORTHLAND SECURITIES, INC.



STEPHEN D. SIMPSON, CFA, joined Northland Securities in December 2008 as a Senior Analyst covering medical technology companies. Mr. Simpson has extensive experience in the health care sector, having worked as a sell-side Equity Analyst at Piper Jaffray and more recently as a Consultant to the health care industry, focusing on the life sciences and metabolic/endocrine disease markets. He has a B.S.L.A. in Japanese from Georgetown University and holds a Series 7, Series 63, Series 86 and Series 87 license.

SECTOR — DIAGNOSTIC SUBSTANCES

(AAZ808) **TWST:** You cover both the medical devices and the life sciences companies. Tell us specifically what you cover in that space.

Mr. Simpson: The stocks I cover are **Bio-Rad** (BIO), **Cardiovascular Systems** (CSII), **Immucor** (BLUD), **ICU Medical** (ICUI), **IRIS International** (IRIS), **Luminex** (LMNX), **Volcano** (VOLC) and **ZOLL Medical** (ZOLL).

TWST: How do you select which companies to cover?

Mr. Simpson: Because I am active in three areas — devices, diagnostics and life sciences — I have the luxury of picking companies where I think there is good value or good growth and an interesting story to tell. As a practical matter, given that I work with a company that focuses on smaller and mid-cap stock, we tend to like to cover relatively under-followed stocks. I'm not terribly interested in being the 18th analyst on a stock, I would rather be one of four or five or six analysts if that's possible.

TWST: Let's talk about life sciences. One of the trends you've talked about is the movement of life sciences companies into diagnostics. Are we still seeing that? If so, why?

Mr. Simpson: We certainly are. There are a few reasons for this strategy. First, it's a logical outgrowth of the technology for the life sciences companies. Second, it allows these companies to tap into a second customer base, and one that typically has a rather good funding behind it because when you develop a test, then you're talking about insurance, and Medicare and Medicaid.

It's not quite as hazardous as grants can be in the research space.

TWST: You have also talked about the emergence of so-called personalized medicine. What exactly is that, and why are we seeing that trend?

Mr. Simpson: Personalized medicine is the idea that you can use genetic information about a patient to better diagnose and treat them. For example, there is a range in how people will respond to blood thinning drug like Coumadin, and you can predict that through genetic testing. You do a genotyping study, and you find out that this person carries one or more traits that make him more or less susceptible to the medicine. And then you can prescribe the correct drug and the correct dose more appropriately. Or maybe a better known example: You can test people for whether or not they have certain genetic traits that make them more susceptible to certain kinds of cancer, like the BRCA genotype for breast cancer. With that information, you can either watch these people more carefully given that you know there is a higher likelihood of cancer developing or, if they do have cancer, sometimes the type of cancer they have will point you in one direction or another as to a more effective therapy. That's really what's driving this. The more we know about patients' individual conditions, individual diseases, the better you can diagnose

them and the better you can fine tune that therapy to get maximum effect and minimum side effects.

TWST: Is there any backlash on that? When science first started talking about genetic markers, some people got

Highlights

Stephen D. Simpson discusses the emergence of personalized medicine and the blurred lines between life sciences and diagnostics. He predicts the use of genetic information in treating patients to become more prevalent and highlights companies that are staying ahead of the curve in R&D within that space.

Companies include: Bio-Rad Laboratories (BIO); Cardiovascular Systems (CSII); Immucor (BLUD); ICU Medical (ICUI); IRIS International (IRIS); Luminex (LMNX); Volcano (VOLC); ZOLL Medical (ZOLL); Millipore (MIL); Life Technologies (LIFE); Abbott Laboratories (ABT); Genzyme Corporation (GENZ) and Alexion Pharmaceuticals (ALXN).

nervous about how that information would be used.

Mr. Simpson: It's an interesting question. I think by and large there are some worries about it, but I think people are generally more worried now about disease than about that type of information. I think the likelihood of having that applied against people is relatively low if for no other reason than the fact that there is so much information out there. The idea is that that everybody is going to be able to process it and exploit it. I think that might be a little bit far-fetched. We have the HIPAA law now for health care privacy, and I think that's gone a long way towards easing some of the concerns. Now if there are risks that insurance companies are going to take people's information and, say you're more at risk of this disease, ergo we're going to charge you more, we're going to deny your coverage — that is a threat. That seems to be one of the things that the health care reform bill was trying to address in terms of what can health care companies can do in regards to pre-existing conditions and denying coverage or restricting coverage. But I think as more and more information becomes available, I think it'll actually perhaps counterintuitively be harder to use against people because sooner or later, it's probably going to come out that we're all vulnerable to some disease or some illness at an above-average rate. And it will just be a matter of more effectively diagnosing and managing your lifestyles to minimize the consequences.

“One of my overall themes is that the lines are blurring between what is the device and what is the diagnostics, what is life sciences and what is diagnostics. Those lines get really blurry.”

tests, like we discussed before.

TWST: As a group, how much are these companies spending on R&D? Do these guys still spend a big percentage on R&D, or does it just depend on the company?

Mr. Simpson: It really depends on the company. But I would say overall, being in this space is almost like being in the semiconductor equipment space. If you're going to be in the life sciences equipment space, you're going to have to spend a lot on R&D if you want to continue to stay competitive and continue growing. I just don't really see anyway around that. Whether you are spending 5%, 10%, 15%, is going to be a company policy decision. But I think if you want to be and stay a player, you're going to have to continue to spend money on R&D because the technology just keeps moving.

TWST: Will we see big changes in life sciences in the next year to five years?

Mr. Simpson: The very nature of the space is change and evolution. There's still so much to

learn and the process is going to require ongoing development, new tools, especially new information systems just to handle the tremendous amount of data that's produced. One of the interesting things about life sciences is ultimately you end up spending a great deal of money and effort on things that maybe five or 10 years before, you barely even knew existed. So I could feel very comfortable predicting that five to 10 years from now, there's going to be some major new avenue in life sciences that maybe right now is just a single article or single journal publication in *Science* or *Nature* that most of rest of us have barely even heard of, and that turns out in a few years to be really important and really exciting.

TWST: Now let's switch to the medical devices side. Give us a sense of what that sector looks like right now.

Mr. Simpson: To some extent, the trend here is still that there really is no trend. There isn't a hot emerging space right now. In the past year, you've seen drug-coated stents or companies working on the spine or biomaterials and so on. That said, I think clinical diagnostics could be a relatively more interesting space this year, as hospital labs are hurting for a lack of skilled labor and, in my view, they have to adopt automation practically out of necessity if they're going to handle all this test volume. I think there's already a trend towards automation in hospital labs, and I think that's going to continue in the near term. Secondary to that and perhaps part of the similar overall theme, diagnostic technologies are going to get increasing attention. And one of the companies I follow, for example, **Volcano Corp.**, they've been successful in terms of communicating the virtues of using intravascular ultrasound and functional measurement in conjunction with balloon angioplasty, and drug-coated stents and so on. I think more and more, we're going to see use of these adjunctive diagnostics technologies to better identify who really needs treatment, what is the exact treatment they need, and how we adequately and properly deploy that treatment. So it's really going to go more from being a “treat

1-Year Daily Chart of IRIS International, Inc.

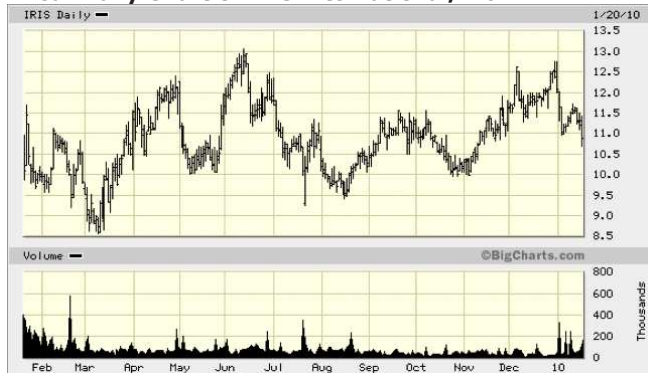


Chart provided by www.BigCharts.com

TWST: Within the life sciences space, what do you see as the R&D priorities?

Mr. Simpson: I suppose the number one priority is staying ahead of the pack in terms of developing systems that are faster, cheaper and easier. More specifically, there is clearly still a major push towards developing systems that can perform sequencing or genotyping much more effectively, including single-molecule sequencing. You hear people talking about sort of the \$1,000 genome as the target, and now clearly a lot of R&D effort is being directed in that direction. There's also a lot of R&D efforts in translating known discoveries or known technologies into diagnostic

and diagnose every patient the same” towards more of a personalized approach, where you really make sure you deliver the optimal therapy for each individual patient, and you do so in the most effective way you can.

TWST: As we move to personalized medicine, are we opening up more treatment for specialized diseases?

Mr. Simpson: I do believe there’s going to be increasing opportunities for specialization. However, I see those companies almost like fireflies: They pop up, they flash, and then they go away. And the reason is they get gobbled up by the bigger acquirers in the space, whether it is a Millipore (MIL) or a Life Technologies (LIFE) or a company like Abbott (ABT). I see them constantly on the prowl for attractive acquisition candidates. If you have a test, a very good test that has good clinical use but for a relatively small application in terms of patient population, more likely than not you’re going to be acquired. Likewise on the drug side, you have a company like Genzyme (GENZ) that is basically devoted towards treating relatively uncommon diseases. I think more and more — for example, Alexion (ALXN) in the biotech space, their approved product is for a relatively rare disease. And I just don’t see those companies staying independent for a particularly long period of time because Wall Street constantly demands growth, constantly demands the new things. And it’s very difficult for a company that may be essentially a one-product company to invest the R&D resources needed to become a two-product company or a three-product company and so on. So many times it’s a path of least resistance to take a lucrative bio bid from a pharmaceutical company or a larger health care company that looks at acquisitions as a way of substituting their own slowing organic growth.

TWST: Are we going to see a lot of M&A activity in either of these subsectors?

Mr. Simpson: Significant in terms of numbers but maybe not so much in terms of the size of the deal. There’re certainly a fair number of companies out there with good technology, with only one or two products. And as I was saying, those can generally be neatly tucked into a larger company, and give that acquirer a boost to the revenue and earnings. For example, in life sciences there are quite a few companies with good ideas or good technologies, but they just don’t have the resources to do a lot with it in a commercial sense, and they can’t build the sales force and do the support, and market against some of these giants. And so I think you’re going to see more and more deals with bigger companies looking to tuck in technology and leverage it across their own platform.

I think this is probably going to be even more true with pharmaceutical companies. Most of the big pharma companies have been cutting their R&D pretty drastically, which has actually been a negative factor for the life sciences space because a lot of times these pharmaceutical companies are major targets for a new technology. But even if pharma cuts down on the R&D, they’re still

going to watch the university labs, and they’re going to watch the startup biotechs. If they see a promising new drug or a new drug platform, they’re going to swoop in and buy it. And in some respect, they’re farming out the risk; they’re letting the biotechs take these things through the pre-clinical and into Phase I or Phase II, and then they’re cherry picking the ones that seem to work or seem more likely to work. I guess in some ways, they’re de-risking their portfolio, even though perhaps they have to spend a little more on the back end to get the technology or the product they want.

TWST: What about financing and credit? Do they rely primarily on stimulus money, grants or money from investors?

Mr. Simpson: There’s definitely stimulus money in the university research lab space, and that in turn distills into the life sciences universe basically by these labs buying the gear, buying the supplies and so on. As far as raising money, that’s still pretty tricky. We’re seeing a few more PIPE financing here and there, and a few more companies filing to go public. But overall, people are still pretty nervous and credit is quite frankly looser for the customers these days than the suppliers. And what you’re seeing in some cases is companies with good balance sheets are using those to extend credit to some of their customers. So sort of a “buy here and pay here” in the health care space.

“The number one priority is staying ahead of the pack in terms of developing systems that are faster, cheaper and easier. More specifically, there is clearly still a major push towards developing systems that can perform sequencing or genotyping much more effectively, including single-molecule sequencing.”

1-Year Daily Chart of Genzyme Corporation



Chart provided by www.BigCharts.com

TWST: Will the ongoing health care debate impact these companies?

Mr. Simpson: I’m not really sure that there’s going to be a major impact to the companies I follow from this so-called reform, particularly in the absence of any real changes to malpractice, tort law, insurance, bureaucracy and so on. Another risk is that some sort of industry tax is going to be levied, and that would certainly be an irritant to the space. But the companies would do what they always do in that kind of situation, they pass it on down to the consumer. I suppose it’s a credible thesis that expanding the access and availability of health care will mean more preventative care,

more testing and so on, so we'll have to wait and see.

The interesting thing about this reform is it strikes me more as a plan to give health insurance to everyone without really going back and trying to reform the insurance process and to reform some of the factors that go into it. Doctors still have to perform their duties mindful of the risk of malpractice, which means do they order more tests than they really want to, and do they treat more conservatively for fear of lawsuits? This bureaucracy slows things down and adds costs. Insurance companies are very reluctant to pay for whatever they deem as experimental therapies. That certainly hurts some companies and slows down medical advances. There's clearly still a need to talk about end-of-life care and a more efficient use of resources. A lot of time, people spend the last few months or weeks of their life with a lot of painful, invasive interventions that aren't really going to add more than a couple of more weeks to their life. They're expensive, they're invasive, but a family is going through a traumatic event, and they want to do everything they can for this person because that's the common thought — that the more you do, the more that reflects that you really care about this person. Unfortunately, it's proven very difficult if not impossible to have a rational sane discussion about what's really the right thing to do. If an elderly person only has a few more years of reasonable life expectancy, where do you say, "Okay, let's stop the intervention, and let's find a comfortable, pleasant hospice so they could have some dignity, and be free of pain and be comfortable for those last weeks or months." Like I said, that's just not a conversation that people seem to be ready to have. Given the enormous amount of money that goes into treating people in their last days and weeks, until we tackle some of these issues, you're not really talking about reform in a sense that's going to really matter much to the device or life sciences industry.

TWST: Who do you like in each of these subgroups and why?

Mr. Simpson: My favorite ideas right now are **Luminex** in the life sciences space, and **ICU Medical** and **Volcano** in the devices space, and **IRIS** in the quasi-device diagnostic space. One of my overall themes is that the lines are blurring between what is the device and what is the diagnostics, what is life sciences and what is diagnostics. Those lines get really blurry. But again **Luminex** in the life sciences, **ICU** and **Volcano** in the devices, **IRIS** in the diagnostics. **ZOLL** is also a company that I like a great deal from a fundamental standpoint; they have a relatively new product called the LifeVest, which has been doing exceptionally well for them. But the stock's already had a pretty solid run there. So it's not quite one of my top ideas at this point in terms of investment potential.

TWST: What about the other companies? Have you changed your ratings on any names lately?

Mr. Simpson: Actually, I've been rather consistent, and this is one of the virtues that we were talking about earlier: I have the freedom and the privilege of picking and choosing where I go, which allows me to find good stories and good names.

So I've been fortunate that almost all of my outperforms have done quite well, and I still like the stories. **Luminex** has had a bit of a turbulent year in 2009 in terms of their stock performance, but fundamentally I still really like the business, and I really am excited about the potential for their products and their technology. **Volcano** had come to life here recently from a stock perspective, but they've been doing pretty well and pretty much according to my expectation. **IRIS** might be the one exception. They had a difficult year; it was a very, very tough year in the lab equipment space. For them, they missed a couple of timelines in terms of the FDA. I look at **IRIS** as almost something of an underdog or a turnaround story for 2010. I think, first of all, spending is going to recover in the hospital lab area, which will be good for them — it should enable them to sell more systems, and those systems should in turn lead to more consumables being sold. But I also think that they've made some changes to their management, and I think they're really refocused on execution. And assuming that they stick to their knitting, and do some of these blocking and tackling types of details, they could be in for a solid year.

TWST: Tell us about Northland Securities.

Mr. Simpson: Northland is an investment bank focused on covering quality ideas in the small-cap and mid-cap areas. We're relatively concentrated right now, and I would say as a firm we try to focus on sectors and ideas where we think there can be some sustainable transformative growth. We're not looking to be the "20-somethingth" analysts covering **McDonald's** (MCD) or **Wal-Mart** (WMT). We're out there looking for the undercovered and underappreciated stocks that have not as good a story, but good products and good technology, and good prospect to back all that up.

TWST: Tell us about your background. How did you get to be a medical technology analyst?

Mr. Simpson: One way or another, I've spent pretty much my entire professional life in the medical technology space. I've worked as a medical device analyst, a life sciences researcher and as a consultant for the diagnostic sector, and that's really reflective of my coverage universe, where I touch on and cover all three of those spaces as part of my regular coverage.

TWST: Thank you. (LMR)

Note: Opinions and recommendations are as of 01/14/10.

STEPHEN D. SIMPSON

**Senior Analyst
Northland Securities, Inc.**

45 S. 7th Street

Suite 2000

Minneapolis, MN 55402

(800) 851-2920 — TOLL FREE

(612) 851-5900

(612) 851-5987 — FAX

www.northlandsecurities.com

Emerging Growth Markets in Health Services

LARRY SOLOW CJS SECURITIES, INC.



LARRY SOLOW, Senior Research Analyst, joined CJS Securities in 2006. Previously, Mr. Solow worked at BioPharma Fund from 1999-2006, where he was a health care Portfolio Manager/Analyst. Prior to that, he spent five years with Smith Barney, covering multimedia and health care stocks. Mr. Solow graduated from the University of Maryland with a B.S. in economics.

SECTOR — HEALTH SERVICES

(AAZ811) TWST: What do you cover in the health care sector?

Mr. Solow: At CJS Securities we are all generalists. We don't have industry analysts in a particular sector, and we focus on undercovered small- to mid-cap names. With that said, I happen to have a background in health care equity research, so my coverage list is skewed towards the sector. Before coming to CJS in 2006, I worked on the buy side for seven years as a Portfolio Manager/Analyst for a Luxemburg-based publicly traded mutual fund, which focused on pharmaceuticals, medical products and supplies. Of the 15 names on my current coverage list, seven of them fall under the broad health care umbrella spread across multiple subsectors. I follow **Hanger Orthopedic Group** (HGR), **US Physical Therapy** (USPH) and **Assisted Living Concepts** (ALC), which are service-oriented-type names. **Bio-Rad Laboratories** (BIO) and **Meridian Bioscience** (VIVO) are focused on clinical diagnostics and life science research, while **Haemonetics** (HAE) and **Analogic** (ALOG) fall into the medical equipment category. We look for companies that have a strong financials and are well positioned in industries with longevity. In that sense, it's very difficult to avoid health care, considering its compelling macro trends.

TWST: What is the status of the health care sector?

Mr. Solow: We expect a wide variety of favorable trends to continue to drive multiyear growth across the health care spectrum. These include an aging population, rising life expectancies, improved access to medical care within the U.S. and

abroad, a growing emphasis on physical health and an increased focus on reducing costs. The companies we follow all fit into these multiple and growing needs for health care.

We believe some type of health care reform is inevitable, but it's hard to say exactly what it will look like. While we have seen the initial outline from the Senate and House proposals, what passes final legislation and how that looks five years from now is difficult to assess. When you are adding tens of millions of people to coverage, you should see an initial benefit, which should outweigh any increased costs/taxes. Any level of health care reform will likely expand volumes and benefit most parts of the sector, especially in the first two to three years of implementation. In the longer term, as the realities of rising costs related to universal coverage set in, increased caps and price pressures in certain areas could potentially offset the benefits of increased volumes.

TWST: Is the health care sector changing to meet these needs?

Mr. Solow: Clearly treatments and outcomes are certainly better driven by ongoing research and advances in technology; while the service side continues to expand its offerings, as companies

recognize the needs and rising demands of patients.

TWST: What about diagnostics?

Mr. Solow: I think diagnostics should continue to grow and be a beneficiary of a rising focus on expenses, considering the cost effectiveness they provide. Total diagnostic sales makes up less than 5% of health care costs in the United States but play a role in greater than 50% of eventual treatment options and corresponding

Highlights

Larry Solow takes us through his top picks in the health care services industry, highlighting his favorite name in the blood management subsector, a space he views prime for growth. He also discusses the assisted living market and explains the expanding global market for diagnostics.

Companies include: Hanger Orthopedic Group (HGR); US Physical Therapy (USPH); Assisted Living Concepts (ALC); Bio-Rad Laboratories (BIO); Meridian Bioscience (VIVO); Haemonetics (HAE) and Analogic (ALOG).

expenses. There are certain areas where you could make a legitimate argument that doctors are doing too many tests just to cover themselves from liabilities. But in general, diagnostics are underused and underpenetrated. Generally, the quicker a patient is correctly diagnosed, the sooner they can be cured or efficiently treated.

TWST: Within the companies you cover in the health care sector, who do you like and why?

Mr. Solow: One of my favorite names is **Haemonetics**, whose focus is on blood management solutions. The company is a leading provider of automated blood processing products for donors and surgical patients worldwide, with 85% recurring revenue from consumable sales to its embedded base of proprietary machines. Its donor collection devices split up the three main components of blood — plasma, platelets and red cells — allowing for higher quantities and more efficient collection, while returning the unused components to the donor. Its surgical blood salvage systems enable surgeons to collect the blood lost by a patient

during or after surgery, clean that blood and have it available to transfuse back to the patient, reducing complications and costs. Its competitive advantage comes through a suite of integrated data management systems for blood collection, which has driven its market share in plasma collection from 40% in 2004 to over 70% today. Product sales have been driven by rapid growth in plasma disposables — 35% of FY10E sales — which have risen nearly 20% annually for the last three years. Market fundamentals and visibility remain strong, with a growing installed base. While this rapid growth will likely slow as a supply shortfall has now aligned with end market demand, double-digit growth in plasma disposables is expected to continue for the next several years, driven by rising use of plasma-derived pharmaceuticals and IVIG therapy — a \$10-plus billion market. Industry plasma collections are expected to rise 7% to 9% over the next several years, with the company outpacing this growth modestly through market share gains and improved pricing. A “wild card” in the plasma story is further penetration into Alzheimer’s treatment, which would drive significant growth. Phase II results demonstrated a strong benefit and given IVIG therapy’s known safety profile, the remaining question is whether the cost of the therapy — upwards of \$50,000 per year — is worth the benefit. Large Phase III randomized clinical trials are scheduled for completion in the 2011-2012 time frame, however, we expect an interim look at results by year-end 2010. Conservative market estimates, which assume only 1% penetration of the entire Alzheimer’s population, would increase plasma collection volumes in the United States/Germany — the two largest markets — to \$35 million per year from the current \$20 million. Five percent penetration, which could prove more realistic assuming therapy is effective, could drive collections up three or four fold.

Blood shortages and cost inefficiencies at hospitals and blood banks offer multiple opportunities, including a more consultative approach that focuses on management of the supply

chain from donor to patient. The company is implementing its proven success in plasma solutions to blood management at hospitals with its growing portfolio of customer solutions. Hospitals’ increased focus and desire to better manage their blood supply and lower costs are expected to drive **Haemonetics’** efforts. It has built a foundation of scalability for small to larger institutions, and devised a repeatable program with information management tools and a comprehensive process of implementation, which includes economical and clinical data to back strategies. Penetration of so-called “blood management accounts” at key hospitals across the country is slowly on the rise, and could begin to accelerate as pressure to rein in costs and comply with government regulations increases.

Haemonetics continues to progress towards its goal of entering automation of the whole blood market during 2011 with a premium product to meet customer needs. This could transform collection and processing of whole blood, which remains the dominant donor market. The company

is targeting this \$1.6 billion global market with an improved pump and smaller needle versus the current slow gravity draw and large needle, which lead to inconsistent quality, wasted blood and donor discomfort. The company’s product leverages its information technology, and includes a fully automated and networked blood data and transport system versus the current inefficient manual systems, which yield a 5% discard rate, significant dollar waste and regulatory fines.

“We expect a wide variety of favorable trends to continue to drive multiyear growth across the health care spectrum. These include an aging population, rising life expectancies, improved access to medical care within the U.S. and abroad, a growing emphasis on physical health and an increased focus on reducing costs.”

1-Year Daily Chart of Haemonetics Corp.

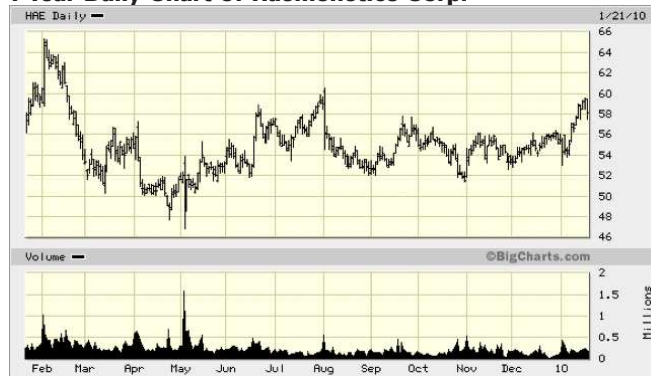


Chart provided by www.BigCharts.com

Another stock I like is **Hanger Orthopedic Group**, which is more of a service provider and customized tailor of orthopedics and prosthetics rather than an actual manufacturer. The company is the largest owner and operator of orthotic and prosthetic (O&P) patient care centers in the United States, which are expected to continue to benefit from favorable macro trends, including an aging population and increasing emphasis on physical health. The O&P industry is characterized by stable recurring revenues due to the need for periodic maintenance, modification and replacement of

the devices. The average replacement time is one to three years for orthotics and three to five years for prosthetics. In prosthetics, a majority of visits are returning customers, while approximately one-half of orthotics patients are recurring, as some fully recover from injuries/disabilities. Business fundamentals remain strong with limited impact from the economy, and we are encouraged about the multiyear outlook. The company has a greater than 25% share of O&P patient service centers in the United States and continues to be a consolidator through small complementary accretive acquisitions. Demand for prosthetics and orthotics is expected to continue to rise, and we project consistent mid-single-digit revenue growth for the next several years, with expanding margins driven by operating leverage.

The “wild card” in the **Hanger** story and the potential for significant upside is the opportunity for its in-house manufactured product, WalkAide, which could drive substantial profit growth in 2011 and beyond. The product is worn around the ankle and contains a microprocessor that helps restore communication between the brain and the foot in people with a condition known as drop foot syndrome, caused by a neurological paralysis that makes walking extremely difficult. The potential target market is large with 5 million combined stroke survivors, multiple sclerosis (MS), cerebral palsy and other spine trauma patients in the U.S., plus 500,000 annual stroke survivors and 50,000 newly diagnosed MS patients each year. An estimated 25% of these patients would qualify for WalkAide, or nearly 400,000 people. A good frame of reference is the 120,000 annual **Hanger** patients treated with an ankle foot orthotic (AFO device), with a significant percentage because of drop foot. The product was approved by the FDA a few years ago but is currently not widely reimbursed by private insurers or Medicaid/Medicare. Currently, it contributes about \$10 million in sales off a base of \$800 million, so it’s not really moving the needle. We expect Medicaid reimbursement approval in 2011, with increasing coverage by private insurance over the next 12 months. We believe this product could contribute over \$100 million in sales within three to four years, with gross profit margins in the 80% range — nearly double the current corporate average.

A third stock I like is **Assisted Living Concepts**, which is a leading operator of assisted living facilities in targeted middle-market suburban communities with favorable demographics. It owns 70% of its 200-plus properties, a greater percentage than its public comparables, which provides it with operational and financial flexibility. The target market is large and growing, driven by the needs of an aging population and recognition of the benefits — and affordability — of assisted living. The industry is highly fragmented, with only a handful of national providers who can benefit from economies of scale, including purchasing power and leveraged corporate overhead. Supply of senior housing has stabilized over the last few years, following overbuilding in the late 1990s and early 2000s. However, a significant drop in new construction as a

result of the economic downturn is expected to improve the supply/demand imbalance over the next few years. In late 2006, **ALC** made the strategic transition to shift its patient mix to all private pay and essentially eliminate Medicaid exposure. Private pay offers substantially better economics, including 30% higher pricing and rising rates as opposed to continual pressure from government reimbursement. During this shift, occupancy has fallen from 85% to 65%. The transition is in the late stages, as revenue from Medicaid has been reduced to 5% from 21%. Margins are at historic and industry highs despite the significant drop in occupancy, aided by the substantial improvement in mix towards the more profitable private pay. The business model is operationally leverageable given a high fixed-cost base, which could drive considerable margin expansion on modest improvement in resident utilization.

We believe growth can accelerate as the economic environment improves, industry supply/demand tightens and occupancy rates rise. The shares trade at generous discount to public competitors despite similar margins, more room for growth, a stronger balance sheet and less exposure to Medicaid.

“I think diagnostics should continue to grow and be a beneficiary of a rising focus on expenses, considering the cost effectiveness they provide. Total diagnostic sales makes up less than 5% of health care costs in the United States but play a role in greater than 50% of eventual treatment options and corresponding expenses.”

1-Year Daily Chart of Assisted Living Concepts, Inc.

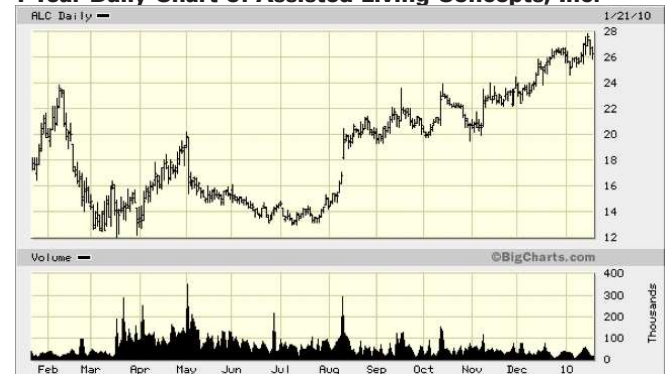


Chart provided by www.BigCharts.com

Finally if I may, let me take the opportunity to mention **Meridian Bioscience**, whose focus is on rapid testing of underdiagnosed conditions in disease states, where there is not a lot of competition. Since inventing the first rapid 10-minute strep throat test 25 years ago, **VIVO** has grown to become a leading provider of over 150 diagnostic products in a wide variety of formats, targeting underserved infectious diseases where a rapid diagnosis is important. **Meridian** primarily serves the worldwide acute care hospital and reference labs markets. The company develops, manufactures and distributes inexpensive self-contained test kits used on humans where a physician can rapidly — 10 minutes to two hours — detect what is causing the symptoms so the appropriate therapy can be determined. Its consumable test products are easier to use, faster — with results in minutes/hours rather than two to five days — and less capital intensive than competing

solutions. There is an ongoing shift from conventional testing performed by highly trained medical personnel that require lengthy turnaround times to simple-to-use, technically advanced tests, which offer expedited results. The global market for diagnostics continues to expand as new and existing infections emerge and spread rapidly, novel therapies become available and access to health care in international markets improves as standards of living rise. The pressures to reign in health care costs have accelerated the use of rapid diagnostics, leading to better diagnoses and getting proper medication, faster recoveries, shorter hospital stays and lower overall treatment expenses. **Meridian** is poised to launch its initial product in molecular diagnostic testing in *c.difficile*, a hospital-acquired stomach virus, under the brand name **ILLUMiGene** during 2010. We expect additional indications to follow over the next 12 to 24 months, which could reinvigorate revenue growth which slowed in 2009 to the mid-single-digit range after growing at a 15% CAGR for the last six years. Significant operating leverage, improved automation and efficiencies have led to annual 50 bps to 100-plus bps margin improvements for five consecutive years, a trend we expect to continue.

TWST: What is your background?

Mr. Solow: I have a finance education and began working on Wall Street in the mid-1990s after graduating from the University

of Maryland, College Park. I started my career as a sell-side Associate Equity Analyst for Smith Barney, where I covered pharmaceutical and biotech companies for nearly three years, and advertising/media stocks for two years. I left Smith Barney in 1999 to join BioPharma Fund — subsequently bought out by Fortis Investments in 2006 — a Luxembourg-based health care fund with most of its investments and a majority of employees based in the United States. The role of a generalist and the ability to look across sectors for ideas has always intrigued me. This brought me to my current position as a Senior Equity Analyst for CJS Securities.

TWST: Thank you. (LMR)

Note: Opinions and recommendations are as of 01/18/10.

LARRY SOLOW
Senior Equity Analyst
CJS Securities, Inc.
50 Main Street
Suite 325
White Plains, NY 10606
(914) 287-7600
(914) 287-0448 — FAX
www.cjs-securities.com

Trends in Life Science Tools & Diagnostics

DAN LEONARD FIRST ANALYSIS CORPORATION



DAN LEONARD is a Vice President at First Analysis Corporation who specializes in research and investment in life sciences tools and diagnostics, and other selected areas of the chemistry-enabled sector. He provides research coverage of leading private and publicly traded companies in his sectors. His work has been cited for excellence in the *Financial Times*. Prior to joining First Analysis in 2002, Mr. Leonard was an Analyst in the life sciences division of Simon-Kucher & Partners, where he specialized in pricing strategy

for pharmaceuticals. He earned an MBA from the University of Chicago and a bachelor's degree in economics from the University of Michigan.

SECTOR — DIAGNOSTIC SUBSTANCES

(AAZ810) TWST: Please tell us about your coverage within the health services sector.

Mr. Leonard: I cover the life science tools and diagnostics group. These are companies that provide tools and services to understand chemistry and biology, and apply this understanding to both drug development as well as clinical diagnostics.

TWST: What are some of the big issues for this group right now?

Mr. Leonard: In the tools group, the big themes would be that large pharma R&D budgets are under pressure, and the large pharma R&D pie actually shrank in 2009. But in 2010 this pie probably won't grow, but I don't think it's getting any worse. The funding environment for small biotech companies, those companies that burn cash, is actually getting a little bit better following a very poor 2009 and late 2008. Also academic and government-sponsored research support could be improving worldwide. You not only have the NIH stimulus in the U.S., but you have some science stimulus programs happening around the world in places like France and Germany. And it looks like the Japanese science spending is actually improving a bit and showing the first signs of life in a long time.

TWST: How significant is the regulatory environment

in these two subsectors? Are they heavily impacted?

Mr. Leonard: It is very significant on the diagnostic sector. The tools sector is not regulated, but in the diagnostics space, that's very heavily regulated.

TWST: Will health care reform impact them?

Mr. Leonard: Perhaps, but it's still a little unclear. There could be two impacts. One, there could be a negative impact if the diagnostics companies are expected to pay a medical device tax, and that looked like it would be a big deal for a while. The initial proposal I think was a \$4 billion annual tax on the medical device companies. Since then, at least in the most recent version of health care reform that passed the Senate on Christmas Eve, that's been paired down quite significantly. The most recent fee was \$2 billion, and there are exceptions that would apply to the diagnostics companies. So for instance, Class I medical devices and Class II medical devices, which sell for less than \$100, wouldn't be part of the tax. It looks at the end of the day like the negative side is pretty benign. On the positive side, if you have increased health care coverage, you could potentially have more people going to the doctor and having more testing

ordered. That could be a positive for them.

TWST: What other opportunities are out there?

Highlights

Dan Leonard discusses the overriding themes in the life science tools group, including a shrinking large pharma R&D budgets, and increased support from academic and government funding. Mr. Leonard also highlights the molecular diagnostics group, which has created a new market and provided excellent growth opportunities for companies in this space. He advises investors pay close attention to the FDA's strict approval process for diagnostic products and be aware of new industry trends, such as next-generation sequencing. Companies include: Qiagen NV (QGEN); Hologic (HOLX); Gen-Probe (GPRO); Roche Holding (RHHBY.PK); Illumina (ILMN).

Mr. Leonard: Growth in the diagnostics industry is driven by a lot of new product cycles, and that is driven by technology. So one of the hotter spaces in diagnostics right now is molecular diagnostics, and that's just the name given for diagnostics tests where your target is nucleic acid. That's still a relatively new technology, and that's been able to create markets that didn't exist before — one of which, for example, would be HPV testing, human papillomavirus testing. And persistent HPV infection is a cause of cervical cancer. Digene started marketing an HPV test several years ago, and they were later acquired by **Qiagen** (QGEN). And that market is still very underpenetrated, and it's a very fast grower for **Qiagen**. And that's why you have other companies, like **Hologic** (HOLX), which recently entered that market through its acquisition of Third Wave. **Gen-Probe** (GPRO) is entering that market; **Roche** (RHHBY) is entering that market in the U.S. in the next couple of years. So it's a good growth area.

You also are seeing some growth in companion diagnostics, or diagnostic tests used in conjunction with a pharmaceutical. So the result of the diagnostic informs upon your treatment decision of what pharmaceutical to use. So for example, KRAS mutation testing — mutation of the KRAS gene — is a predictive biomarker for response to EGFR inhibitors, such as Erbitux and Vectibix. A paper published on this in *The New England Journal of Medicine* implicated the gene mutation with response of these drugs. The FDA then changed the label for both Erbitux and Vectibix to include this information. There are organizations such as The National Comprehensive Cancer Network, which updated their guidelines to recommend their oncologists to determine a patient's KRAS status as part of their pre-treatment workup for patients diagnosed with colon cancer. So that market is a growing market, and there are all sorts of others. **Qiagen** is a company that talks about having 15 partnerships with pharmaceutical companies to develop these companion drugs. So that could be a real market, each of those markets individually. The KRAS testing market, maybe that's only a \$50 million market for the diagnostics manufacturers. But if you start stacking a bunch of \$50 million markets on top of each other, you can get something that's meaningful.

TWST: What makes a company a good pick in the life sciences group?

Mr. Leonard: Right now I am more predisposed to recommending stocks that have a good amount of exposure to academic and government-sponsored research in the tool space because I think that's a good growth trend worldwide currently. I'm also recommending names that have good product breadth because there is a lot of competition for some of the companies that have a very niche and specific focus on one or two product areas. There can be pretty heavy competition.

One of the big trends in life science tools, which I didn't mention, the big product cycle is next-generation sequencing. The cost of sequencing a person's genome has fallen dramatically in the

past several years, and **Illumina** (ILMN) just came out and said they introduced an instrument which can sequence a genome for less than \$10,000 in consumable cost. There is another private company called **Complete Genomics**, which is currently selling human genomes for \$20,000, and they expect to be selling them for probably around \$10,000 at some point in 2010, and that's their all-in cost to the customer. So whereas with the **Illumina** tool, if you say it's a \$10,000 genome, that's really only your cost of consumables, and your actual cost of delivering a genome is probably three times

that. But for **Complete Genomics**, they sell it for \$10,000 — that's your all-in cost. So that's an incredibly competitive area right now, and there are well north of a dozen companies that are trying to develop the next sequencing technology. Those areas for investment can be a little bit dangerous, but the stocks, if you pick them right, can work out phenomenally.

TWST: What do you look for in diagnostic companies?

Mr. Leonard: The trends are a little bit different in diagnostics.

They are not as exposed to the academic and government funding trends. What I generally look for is valuation, growth potential, how penetrated are their target markets for their key products, how many risks are on the horizon versus their peers, and then evaluate all that in conjunction and make our recommendations.

"Right now I am more predisposed to recommending stocks that have a good amount of exposure to academic and government-sponsored research in the tool space because I think that's a good growth trend worldwide currently."

1-Year Daily Chart of Qiagen NV

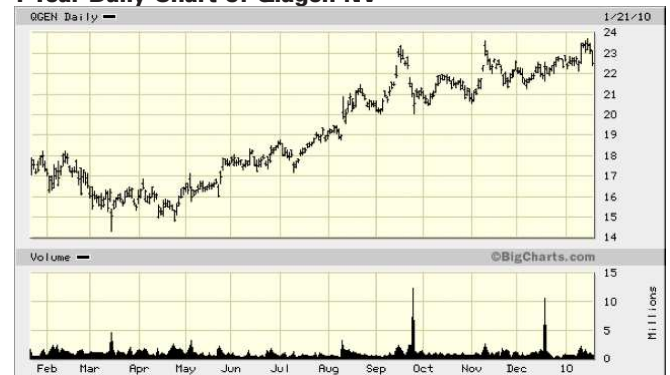


Chart provided by www.BigCharts.com

TWST: What do these companies spend on R&D?

Mr. Leonard: The companies tend to spend about 10% to 20% of their revenue on R&D; 10% is for the tools companies, and some of the faster-growing tools companies like an **Illumina** might spend closer to 20%. The diagnostics companies, some of them spend 20%, 20%-plus, like a **Gen-Probe**. So that's generally a big cost.

TWST: You said you didn't think 2010 would be as bad as 2009. How will these two subsectors evolve over the next couple of years?

Mr. Leonard: I think consolidation is a pretty prominent trend in both subsectors, and that tends to be driven by a company's desire to fill gaps in their product offering as well as leverage their

existing channel. So I think that will continue. Over the next several years, you will have more and more acquisitions, more companies will get larger.

TWST: What are going to be the big issues for them in the next couple of years?

Mr. Leonard: I think you are going to have many more new product cycles. Also the FDA is becoming stricter on what they will allow, so more and more diagnostics products will have to go through the FDA process before they can be sold. You will have more FDA-approved products out there.

TWST: Tell us about your background. How did you become a medical analyst?

Mr. Leonard: Out of college, I went to work for a consulting company called Simon-Kucher & Partners, doing pharmaceutical pricing research. So that got me into health care. Playing with my personal brokerage account got me interested in investing. I then transitioned to First Analysis to get into the investment business, and started covering tools and diagnostics because it seems like there are plenty of growth trends, and we try to cover growth companies.

TWST: Tell us about First Analysis.

Mr. Leonard: We are a Chicago-based firm, have been around since the early 1980s. We have roughly 50 employees. One of our main businesses is providing equity research to institutional investors, and our focus there is on growth stocks. We look to leverage our knowledge in as many ways as possible. So we also have an asset management investment advisory business in private equity with a family of growth private equity funds in the areas we follow on the public side so that we can leverage the knowledge base. Our investment banking team provides transactional services to private and public companies in our areas.

TWST: Thank you. (LMR)

Note: Opinions and recommendations are as of 01/16/10.

DAN LEONARD

Vice President

First Analysis Corporation

1 S. Wacker Dr.

Suite 3900

Chicago, IL 60606

(312) 258-1400

www.firstanalysis.com

FIRST ANALYSIS SECURITIES CORP.

IMPORTANT DISCLOSURES AS OF WEDNESDAY, JANUARY 20, 2010

Illumina Inc. (Symbol: ILMN)

Disclosure notes: NONE*

Qiagen N.V. (Symbol: QGEN)

Disclosure notes: NONE*

Gen-Probe Inc. (Symbol: GPRO)

Disclosure notes: FASC expects to receive or intends to seek compensation for investment banking services from this company within the three months following the publication date of this document.*

GENERAL DISCLOSURE: The compensation of the research analyst(s) principally responsible for this discussion is indirectly based on (among other factors) the general investment banking revenue of FASC. FASC considers all the companies covered in its research reports to be potential clients.

Update on Life Science Tools & Diagnostics

I S A A C R O L E E R I N K S W A N N & C O M P A N Y

ISAAC RO covers the life science tools and diagnostics sector for Leerink Swann. In 2009 *Institutional Investor* named Mr. Ro a Best Up-and-Comer in medical supplies and devices. Additionally, Leerink Swann's coverage of life science tools ranked number two in the 2009 Greenwich Survey. Mr. Ro joined Leerink Swann in 2004. Prior to Leerink Swann, he was a Research Associate at Independence Investments (now Lee Munder Capital), covering health care and consumer stocks. Before that, he spent two years as a Consultant at the Aberdeen Group and conducted orthopedic research at Harvard Medical School. Mr. Ro holds a B.A. with honors in history and pre-med from Middlebury College.

SECTOR — DIAGNOSTIC SUBSTANCES

(AAZ809) TWST: What specifically in life science tools and diagnostics do you cover?

Mr. Ro: About 25 companies. I cover **Life Technologies** (LIFE), **Illumina** (ILMN), **Thermo Fisher** (TMO), **Waters** (WAT), **PerkinElmer** (PKI), **Bruker** (BRKR), **Millipore** (MIL). I cover **Gen-Probe** (GPRO), **Hologic** (HOLX), **Qiagen** (QGEN), **IMA** (IMA), **Genomic Health** (GHDX), **Myriad Genetics** (MYGN), **Luminex** (LMNX) along with a number of other companies.

TWST: Generally speaking, what is the status of the sector right now? How do things look for life science tools and diagnostics?

Mr. Ro: Pretty good, actually. Obviously 2009 was a tough year for everybody. But these companies weathered the storm reasonably well because they have pretty durable end markets. In some cases, they're levered to improvements in industrial spending. The stocks actually outperformed the markets quite well. The life science tools group was up 50% last year, and the diagnostics group was up nearly 30%.

TWST: Does it look like that that trend will continue?

Mr. Ro: One should be cautious. There are a couple of pieces to it. On the fundamental side, businesses continue to do better. However, the stocks reflect a lot of that already. So I don't think we'll see as much upside this year as we saw last year. The broader health care industry hopefully will do better because health care reform should hopefully clear up in the next month or

two, and once you get clarity there, investors can reinvest in these companies. On a relative basis, you may not see as much upside this year. But from a fundamental perspective, I do think these companies have a pretty good 2010 lined up.

TWST: How important is innovation in this sector?

Mr. Ro: I think there are two ways to look at it. As you might imagine, growth investors typically look for innovation to drive stock performance. So on the one hand, you're seeing a lot of innovation in this life science tool space as it relates to genomics. You have companies like **Illumina**, for example, who earlier this week launched a pretty impressive new DNA sequencer, the HiSeq 2000. And that's something that really positions us to change the field of research, and I think it is a hallmark example of the kind of innovation these companies are capable of. On the diagnostics front, you have two things going on. On the one hand, you have an effort by a couple of companies to move their products out to the point of care, so care is administered locally — you might even have the test actually administered right at the bedside. You get faster turnaround time on the results. Doctors can make quicker decisions as to how to treat the patient. So that's one area in diagnostics that's shifting. The other piece in general in diagnostics would be that more and more, you're seeing what I call "companion diagnostics" in drugs.

Companion diagnostics are tested or designed very specifically to help to realize what therapy a patient should get.

TWST: Who are the leaders in genomic testing?

Highlights

Isaac Ro discusses his forecasted trends in the life science tools and diagnostics segments, noting that stocks in both spaces outperformed the market in 2009. Mr. Ro also highlights innovations in the area of genomics, signalling which companies are leading the way in that field. Among other topics, he mentions health care reform and upcoming M&A activity.

Companies include: Life Technologies Corp. (LIFE); Illumina (ILMN); Thermo Fisher Scientific (TMO); Waters (WAT); PerkinElmer (PKI); Bruker (BRKR); Millipore (MIL); Gen-Probe (GPRO); Hologic (HOLX); Qiagen NV (QGEN); Inverness Medical Innovations (IMA); Genomic Health (GHDX); Myriad Genetics (MYGN) and Luminex (LMNX).

Mr. Ro: Genomics is really led by a good margin at this point by **Illumina**, ILMN. I just raised my price target for them because I believe this company is innovating not only in genomics, but they actually also have an entree eventually into the diagnostics world as well. So there are a couple of things that, over the next couple of years, that are going to change the market and could take them well over \$1 billion in revenues.

TWST: What exactly will change the market?

Mr. Ro: The first product is this high-speed DNA sequencing platform I mentioned earlier that will provide, at this point, probably four times the amount of genetic information per experiment and is at least two times better than the next best machine in the industry. They are really making geometric improvements in their performance every year or so. And I'm not sure about the next 10 years, but we're still in the very steep part of the curve where the performance is still doubling in very short intervals. So that's the first product, the HiSeq 2000 system from **Illumina**. The next piece that they are working on is bringing the sequencing technology to the masses. So it's definitely something that every research lab would have. We can think about bringing the cost down to a point where anybody can do it. That's something that would really expand the market again. And so they've got a technology still in the stock works that potentially emerges later this year or early next called Avantome, and there's very little known about it other than it's going to be ultra low cost, relatively high throughput. It would be about the size of a microwave and could go in every research lab.

On the diagnostic front, people that are really innovating are two companies, **IMA**, **Inverness Medical**, out of Boston, who is putting an effort on that point of care technology dimension, and then **Qiagen**, QGEN, which is a company out of Europe that's having a pretty good run; they are building out a franchise in developing diagnostics that are involved in point of care. On top of all of it, what they're trying to do is to become a leader in the field of molecular testing. So instead of using a blood sample or cellular analysis, you could actually look at the genetic level. So **Qiagen** and **IMA** are two companies that are really leading the charge there.

TWST: Will we see much M&A activity in this sector?

Mr. Ro: Yes, this week you've seen at least three or four deals, most of them are large public companies buying small private companies. At JPMorgan's health care conference in San Francisco this week, I saw at least a dozen high-quality companies that are trying to approach the IPO market later this year. The capital markets may not support that many deals, but my guess is that you'll see at least two or three IPOs of note in life sciences and diagnostics this year, and double or triple the number of M&A events.

TWST: You mentioned the IPOs. Why are they preparing to approach the market now? Is it because of timing or technology, or because the market is ready?

Mr. Ro: The companies are ready because a lot of the innovation is there. The investors are ready because they're not quite as beat-up as the last year and a half. So that's kind of a press

point of what valuation these companies are going to achieve because investors are more likely to take a haircut of evaluation; they're more willing to pay it now than they would have in 2007 and 2008. My sense is that you'll have only the highest-quality companies really achieving IPOs, and a lot of them going through M&A access just because it's a lot less hassle.

TWST: Is it important for these companies to have an international presence?

Mr. Ro: There are two ways to look at it. On the life science tools space, those companies have already done that. Most of those companies generate 50% to two-thirds of their revenues outside the U.S. But in diagnostics, it's still a U.S.- and Western Europe-driven market. So one of the reasons why point of care is interesting is

if you think about emerging markets, the ability to test on site in a community where you don't have hospitals and structure of size is very helpful. That's something that, for example, **IMA** is working on with an HIV assay in Africa. Those are things that I think you will see more of. And in the emerging markets, clearly there is enormous growth there. My sense is that you'll see both sides of the industry working that way going forward.

"I think diagnostics as a result are probably a better place to be in health care, post health care reform, than most others. But by no means is there going to be a straight shot."

1-Year Daily Chart of Illumina, Inc.



Chart provided by www.BigCharts.com

TWST: Is health care reform a big issue?

Mr. Ro: On the life science tools space, not really. Those companies don't really have exposure to health care reform or FDA regulation. Having said that, if you look towards what else is going on structurally, one of the reasons why these stocks have done very well over the last year is the stimulus package. The stimulus package included a big booster shot for the NIH budget, and the National Institutes of Health is the single largest funding source for most of these companies in the research setting. The \$30 billion-a-year annual budget and the stimulus package included another \$10 billion to be spent largely over the next two years in the NIH. A lot of these companies are going to harvest the benefit of those dollars this year and next. That's something that I think really is more important than

health care reform. On diagnostics, it's a little different. At this point, it looks like health care reform is a basic expansion of coverage for people who didn't have it before but without significant new revenue sources to pay for it. What that means is it gets a little bit harder to get reimbursed for all these various products as you're spreading it a little thinner, so people will wait longer to get in for an MRI and that kind of thing. Those types of impacts of the system obviously lower the pricing environment for these products. The good news is — and this is the offset — that diagnostics are generally perceived to be ways in which you could be more efficient and cut costs. So for example, if you can better identify who is going to respond to a high-cost cancer therapy using a diagnostic test, that test would have value. Similarly, if you can prevent people from getting unnecessary sensor or pacemakers put in by using a test, it better indicates your type of chest pain, for example, that would be valuable as well. I think diagnostics as a result are probably a better place to be in health care, post health care reform, than most others. But by no means is there going to be a straight shot.

"My sense is that you'll have only the highest-quality companies really achieving IPOs, and a lot of them going through M&A access just because it's a lot less hassle."

kinds of things that **Wal-Mart** does well, to the large customers. So whether it's government labs or drug companies, they have the scale. The other piece would be **Life Technologies**, LIFE, which is a similar company that has a more esoteric and a higher-margin catalog of products, and they're more focused on the genomic field than others, but they also have that **Wal-Mart** approach. They have a very broad catalog, and they are going to do quite well. Their relative exposure to the NIH budget is higher than almost any other company in the field.

TWST: How about up-and-comers, companies that aren't quite there yet but may be on the verge of doing well?

Mr. Ro: That's interesting. It depends on how you look at **Illumina**. **Illumina** is going to do this year about \$800 million in sales. This is going to be less than 10% the size of **Thermo**, but if you look at the growth rate they are on, their earnings

growth is going to be in excess of 30% compounded over this year, 2009 to 2012 — that's my estimate. With that kind of an earnings power profile, that's 2x the industry growth rate. So as much as they've had a huge run, the stock has probably a \$4.5 billion market cap, they are still very much an up-and-comer. They are really coming into their own, I think, over the next two years. That conversation will fade and people will really think of them as an industry juggernaut as they expand into areas like diagnostics.

TWST: When you are weighing companies, what do you look at?

Mr. Ro: You need to manage the expectations of investors very carefully because you have all these cross currents we've talked about, which make it hard to forecast. Companies that deliver on their results consistently are hard to find in this space, but they are the ones that do always get the credit. The second thing is of course strategy because there are a million different directions you can go in, and the companies that identified the growth opportunities and executed on them have gotten credit. That's **Illumina**. When **Illumina** bought the key asset that gave them this sequencing technology in late 2006, it was a dilutive acquisition that cost \$600 million, so it was big deal for them at that time. In contrast, **Thermo Fisher**, the way they got to where they are now was in 2006 acquiring **Fisher**. **Thermo** was for the most part an equipment company, and they bought this big catalog business. **Fisher**, which had all this distribution reach that gives them this whole **Wal-Mart** effect, has served shareholders quite well over the last few years. They are at a bit of a crossroads now because they need to do the next big thing, and that's what I think will unlock a lot of value for the stock, is if you see them deploying their capital aggressively this year into new growth opportunities.

TWST: Give us some background on **Leerink Swann**.

Mr. Ro: **Leerink Swann** is investment bank based out of Boston that was founded 15 years ago and entirely focused on the health care industry. We cover 150 health care stocks across 10 sector teams. We probably have the largest footprint in health care

1-Year Daily Chart of Thermo Fisher Scientific



Chart provided by www.BigCharts.com

TWST: You mentioned **Illumina** already. Who else do you like in these sectors and why?

Mr. Ro: There are two companies in life science tools that I would point out. One is **Thermo Fisher**, TMO. **Thermo** is a \$20 billion company that is effectively the **Wal-Mart** (WMT) of their industry. And as we all know, it worked out pretty well for **Wal-Mart**. **Thermo** is a company that has the broadest portfolio of assets and most importantly the broadest channel. If you think about this industry maturing a little bit, being the 800-pound gorilla, and having the balance sheet and cash flow to really eat up all the little assets that you might want, and also having the distribution reach to grow in — they have, for example, over 1,000 people in China. That market is growing 25% annually, more or less. **Thermo** is growing faster than that because of their relative scale advantage. And they also have the ability to go and pursue volume, pricing and all those

on the Street, and I am one of the 10 analysts that we have covering life sciences and diagnostics. I think one thing that is notable is if you look at the firm's evolution, we've always had a very strong research franchise. And in the last year or so, we augmented the investment banking group with a great team from Merrill Lynch. As an analyst, it's been a good ride; I've been here about six years.

TWST: Tell us about your background.

Mr. Ro: I have been with the firm for six years, and before that I was an investor on the buy side at Independence Investments in Boston, which is now owned by Lee Munder. I did my undergraduate degree at Middlebury College and love to ski in my free time.

TWST: Is there anything you would like to add?

Mr. Ro: I think this sector has had a great run again last year. The hope is that, that can continue this year. But certainly it feels like a stock-picker's market. You've really got to look at these companies not only on a 90-day basis but also the big picture, and

look at the strategy, which is what I think investors are going to appreciate as they look at stocks that they are willing to pay up for. If everything has already had a nice run, now you need to believe in management, you need to believe in strategy for the longer run, and that's what I think is going to separate some of these stocks this year.

TWST: Thank you. (LMR)

Note: Opinions and recommendations are as of 01/15/10.

ISAAC RO
Analyst
Leerink Swann & Company
1251 Avenue of the Americas
22nd Floor
New York, NY 10020
(212) 277-6100
www.leerink.com

Arrayit Corporation (ARYC.OB)

RENE SCHENA is CEO, Chairman and Director of Arrayit Corporation, which was created from the Biotech Division of TeleChem International Inc., a company Ms. Schena co-founded in 1993. Arrayit has emerged as a world leader in microarray technology under Ms. Schena's management. The company received awards in 2002 and 2003 from *Inc. Magazine* as a top-500 fastest-growing privately held company, and in 2005 it was recognized by the *Silicon Valley Business Journal* as the 11th largest woman-owned business in Silicon Valley. Ms. Schena holds a degree in language studies from the University of California, Santa Cruz. She has 25 years' experience in international business, including translation, contract documentation and commodities trading. She worked in commodities trading with a subsidiary of ConAgra (1985-1988) and as a Chemical Import and Distribution Specialist, Department Manager and later President of NuSource Chemical Corporation (1988-1993). Ms. Schena co-founded TeleChem International, Inc., continued the import and export chemical distribution specialty, expanded into government-bid business and expanded again into the biotech sector in 1996.

DR. MARK SCHENA, Ph.D., President, Chief Science Officer and Director of Arrayit Corporation, graduated with a Ph.D. in biochemistry in 1990 from the University of California at San Francisco. In 1995, as a post-doctoral fellow at Stanford University, he published the first paper on microarrays in the premier scientific journal, *Science*, introducing microarrays to the world as a new scientific technology. Acknowledged by his peers for the importance of these accomplishments, Dr. Schena was proclaimed the Father of Microarray Technology by *The Scientist*, a broadly read scientific journal, in 2003. Dr. Schena has authored five foundational books on the subject of microarrays including the bestselling text *Microarray Analysis* (J. Wiley and Sons), and he has published more than 30 important papers in scientific journals. Dr. Schena holds the key microarray diagnostics patent that provides for 100,000 patients to be screened for a health condition in a single, simple laboratory test. In 2001 this discovery was featured in the NOVA television documentary "Cracking the Code of Life," in which Dr. Schena introduced microarrays as a diagnostic tool for the first time. In addition to valuable intellectual property, Dr. Schena has developed products, platforms and services for Arrayit that produce multimillion-dollar sales.

SECTOR — HEALTH SERVICES

(ANM606) **TWST: I would like to begin by asking you to outline the history of Arrayit and give an overview of your business.**

Ms. Schena: Arrayit Corp. is a newly public company as of March 2009. We find our roots as a subsidiary of TeleChem International, Inc., which was founded in 1993 by myself and Todd Martinsky, our Executive VP. We have been pioneers in the microarray marketplace, being one of the very earliest companies in this space, starting in 1997. We have some patented technology, and obviously a lot of trade-secret and other technology that we've developed over the past 13 years, the most important being our printing technology.

TWST: Let's talk about what exactly microarray technology is, if you would.

Dr. Schena: A microarray is a tiny device that contains nearly invisible spots of DNA, protein and other molecules found in the human body, and those spots are arranged in rows and columns on a glass substrate. And microarray devices allow scientists and doctors to explore pathways in the human body with very high precision and high specificity, and allow, for example, the detection of

diseases on a pre-symptomatic basis. So essentially you could think of a microarray as a high-tech biological computer chip. It's a device that processes medical information with very high speed and high precision.

TWST: Is it like an integrated circuit?

Dr. Schena: It is like an integrated circuit in theory, in the sense that microarrays leverage the same three cornerstones as microprocessors — namely parallelism, automation and miniaturization — to process biological information very quickly. Otherwise, microarrays are slightly different. I mean, they don't contain wires and circuits but, as I said, rather pieces of human genes configured at very high density on glass substrates. So for example, to add some tangibility to this, Arrayit has a product called H25K, which contains 25,000 some odd spots. Each spot represents one gene in the human body, and with H25K we can profile and determine the activity of all of the genes in the human body. And we can do that in about 10 minutes. What does that allow us to do? It allows us, for example, to identify the genes that are aberrantly expressed in patients with Parkinson's disease. For instance, patients that do not have the disease once we identify those genes, that gives us a pre-

symptomatic diagnostic for, say, Parkinson's, ovarian cancer, prostate cancer. It also provides the genes that are targets for drug therapies. So by leveraging the information of the human genome, a microarray allows us to decipher biological and medical function very quickly and with very high precision.

TWST: Is a microarray fabricated using photolithography, the way an IC chip is?

Dr. Schena: Right. There are a number of procedures. Photolithography is one means. At Arrayit, we actually use contact printing technology. And our patented contact printing technology has some advantages. One distinct advantage over a technique like photolithography is that we can print both DNA and protein molecules, and protein molecules serve as the basis for two of our products that will be available on the marketplace once we obtain FDA approval. Both our pre-symptomatic ovarian test and our prostate cancer test, both use protein markers for testing purposes. So that's a distinct advantage of the Arrayit platform over, say, a platform that uses photolithography.

"We have been pioneers in the microarray marketplace, being one of the very earliest companies in this space, starting in 1997."

TWST: What kind of research processes do your products replace? What are the advantages that your products bring to this market?

Dr. Schena: The trend is towards miniaturization, and the trend is also towards comprehensive analysis of all of the genes or proteins in the human body as well as controlling costs. So that's really what our technology allows. We are miniaturizing tests and looking comprehensively at all the genes, and we are also offering products that allow us to identify human diseases pre-symptomatically. So a lot of the traditional tests suffer from a number of limitations. Traditional tests require large sample volumes and are relatively expensive to manufacture. They don't allow analysis of all of the genes or the proteins, and typically they have limitations in terms of sensitivity and specificity. So it's really all of those advantages that Arrayit products bring to market. It's essentially, if you will, high technology being brought to bear on health care for the first time, and we would like to think that Arrayit is leading the charge in that respect.

TWST: Do your tests allow many, many more individuals to be tested in one fell swoop?

Dr. Schena: That's certainly one of our core capabilities, and Rene alluded to that a few minutes ago. So we, about 10 years ago, developed and patented a procedure that we refer to as VIP, variation identification platform. That procedure allows us to test on a piece of glass that fits in the palm of your hand up to a 100,000 patients in a single test. So within about 10 minutes, we can deci-

pher the DNA from up to a 100,000 different patients at once. That leads me to my next point, which is something we feel very strongly about — namely that in order to really control health care costs, technological innovation is required, in our opinion. So we can place Band-Aids on different aspects of the health care process in an attempt to control costs, but ultimately cost control is going to be achieved through technological innovation. And again, I'd like to think that Arrayit is an important company in leading that charge.

TWST: Would you give us some examples of microarray technology that's already been commercialized?

Dr. Schena: Certainly. We have been offering products in the life sciences market space since 1997, and we have about 650 products in the Arrayit product line. In addition to that, a number of other companies are operating in this space, and you are probably familiar with them. Affymetrix, Illumina and Agilent are among the other companies in the microarray space who have existing products. So at least in terms of the research market, this is a relatively advanced science. What's relatively new is what we refer to as "translational medicine," where we are transitioning the technology from the laboratory to the bedside in a diagnostic capacity. And that's relatively new in the market. And our first health care products, diagnostic products, are going to be launched this year in 2010.

TWST: Do you anticipate your market will transition from the research science and laboratory setting to, say, the general hospital setting?

Dr. Schena: We'll continue to offer and grow our life sciences business, but obviously the biggest expansion in terms of revenues will be in the diagnostics and health care space. Part of the reason for our continued interest in the research life sciences space is that by offering our equipment, our instruments, tool kits and reagents to basic researchers, that empowers basic researchers to make fundamental scientific discoveries that then become tomorrow's products. And then we can actually license those discoveries back and offer those as commercial diagnostics. So we have a great interest in continuing in the research market, if for no other reason than it provides us a continuous pipeline on a going-forward basis for the diagnostics and pharmaceuticals spaces.

TWST: Does your company require any specific partners, or do you have what you need to go into this market alone?

Ms. Schena: We do have what we need to go into this market by ourselves, but we also are collaborating with other institutions for some of the tests that we have in the pipeline.

TWST: Are you more so designers or fabricators, or a little of both?

Ms. Schena: We have the capability for both. We are very active in research and development of new products, and we have significant manufacturing capacity here at our headquarters in Sunnyvale.

TWST: Let's talk about the capital structure of the company. You've gone public in March, is that correct?

Ms. Schena: That's correct. Yes, we became Arrayit Corp. in March of 2009.

TWST: What was the need for funds?

Ms. Schena: We became a public company in order to have access to capital markets to enter this diagnostic space. We have been self-funded since the founding of the company, but this clinical diagnostics test effort is definitely something that requires

significantly more capital than the research business that we've traditionally been involved in. So we formed Arrayit Corp., and then we also formed a subsidiary marketing arm of our company called Arrayit Diagnostics, Inc., which will handle the marketing of the tests that we are developing here at Arrayit Corp. Then we've also created subsidiary companies of Arrayit Diagnostics, Inc., that focus on each particular disease state that we are tackling. So at this point, we have Arrayit Diagnostics Ovarian, Arrayit Diagnostics Parkinson's and Arrayit Diagnostics Prostate, Inc.

TWST: Would you talk about your debt ratio? Are there any significant stakeholders that prospective shareholders should be aware of?

Ms. Schena: The majority of the company is owned by the board of directors of our company. So myself, Rene Schena, Mark Schena, Todd Martinsky are significant shareholders. We've had some angel investor groups that own a small percentage of the company, and the rest of the market cap of Arrayit Corp. is in the public float.

TWST: Would you tell us about some of the contracts you've won in the last year, particularly with regard to OZ Systems of Arlington, Texas?

Ms. Schena: I would say OZ Systems is a collaboration that we've worked on, but there are other more significant collaborations for us at this time.

TWST: Tell us about them.

Ms. Schena: We won a contract with the Centers for Disease Control this year to do a manufacturing process for them using peptides.

Dr. Schena: The CDC, actually they're using the Arrayit platform to develop tests for anti-terrorism detection. And because there are confidentiality issues, we probably shouldn't say too much about that other than — and it goes back to one of your questions a few minutes ago about the different ways of manufacturing, photolithography versus contact printing. Both the CDC and Sandia Labs are using unique aspects of the Arrayit platform to manufacture microarrays for different applications, including anti-terrorist applications to detect potential bioterrorism agents. Those were contracts that the company received, as I said, from the Centers for Disease Control and from Sandia earlier this year. Ms. Schena can probably tell you about some additional contracts and collaborations that we have ongoing.

Ms. Schena: Another main project, which I guess I mentioned a few moments ago, is our Ovarian Cancer Diagnostic Test, which we call OvaDx. This is a collaboration agreement that we signed just in December with Wayne State University to license some biomarkers that they discovered using the Arrayit platform. We are in the process of collecting the data needed for the FDA approval of this product, and we plan to launch it upon FDA approval, which we are hoping will happen in the fourth quarter of this year.

TWST: Would you tell us about the goal of that product? Is it to determine potential sufferers pre-symptomatically?

Ms. Schena: Yes, that's exactly right. So this will be the first test of its kind that allows ovarian cancer to be detected before a large tumor — let's say, in the Stage III- or Stage IV-type situation — is present. So there is a much higher survivability rate for patients who are discovered in very early-stage cancers. So that's really the goal: to have people be diagnosed sooner so that their

treatment options are greater and more efficacious.

TWST: What do you anticipate would be the cost of your approach to this area?

Ms. Schena: We've got a target price to offer this test in the \$350 range, but we are definitely still doing market analysis to determine that that is the right price point for this product. We've more work to do on that.

"That's really what Arrayit Corporation is all about: bringing high technology to bear in health care to prevent, treat and cure human disease."

TWST: Would you tell us about where your current revenues come from, which are in the range of what, about \$4 million a year, is that right?

Ms. Schena: Our main customer base at this point is the research marketplace. We have not made any clinical diagnostic sales to date. So our customer base is really university laboratories, pharmaceutical companies, government institutions, research organizations, non-profit organizations. So it's really a wide range of customers.

TWST: Are there any other competitors in this area that investors would want to know about?

Ms. Schena: Would want to know about as competitors or just for knowledge of who is in our space?

TWST: Yes, just who is in your space to compare.

Ms. Schena: There are hundreds of companies that are in our space. Going forward in, let's say, a diagnostics-type assay, there has been one company that's gotten a lot of attention lately called Vermillion. They have a different kind of ovarian cancer diagnostic test, which is more of a tumor typing test. But they would be in the same space as we are.

TWST: I noticed that some competitor stocks, Affymetrix and Illumina, had a significant drop in the last couple of months. Is there something going on in the market that investors should know about?

Ms. Schena: Those two companies in particular I think are in a pretty hot and heavy legal battle right now. So that might be affecting it from a shareholder standpoint. Yesterday, Illumina did have an important announcement about their revenues going up and some other projects that they have in the pipeline. So I think in fact their stock went up quite a bit just yesterday.

TWST: So that drop is particular to these two companies, not to your sector?

Ms. Schena: I'd say it's more particular to the companies, not the space. The space is growing by leaps and bounds; it's a very hot area.

TWST: How will the coming change in U.S. health care impact your stock?

Ms. Schena: I think that there is really quite a bit of op-

portunity for us in this health care reform. It's a focus of our company to provide affordable services and services that will impact the cost of providing health care. I mean, low cost has always been an important consideration; I think the effort to reduce cost, to provide care to more people, I think that falls right in line with the philosophy of Arrayit.

TWST: I read something about a microarray referred to as a lab-on-a-chip, is that accurate?

Dr. Schena: Lab-on-a-chip, just personally, I'm not crazy necessarily about that moniker. I think it's okay, it's not great.

TWST: What do you prefer to help people understand what you're doing?

Dr. Schena: I understand microarray is a bit of a technical term, but microarray is an okay description. Human genome on a chip, tiny devices that detect genes and proteins, a medical microprocessor, if you want to use that angle. But essentially, these are testing devices, diagnostic devices that allow us to look very precisely and at very high sensitivity at the function of human genes. That capability allows us to explore and understand disease states for the first time, to detect diseases like ovarian cancer and prostate cancer before the patients themselves can even detect. All of these core capabilities are moving us in a couple of key medical directions from a treatment-based regime to preventative medicine. So that's a significant paradigm shift from late detection to early detection, and towards personalized medicine rather than a one-size-fits-all approach to health care. So I would say microarrays are devices that are enabling preventative medicine, personalized medicine and pre-symptomatic early detection.

TWST: Is there anything else investors should know about your stock, looking ahead over the next 12 to 18 months?

Dr. Schena: One of my favorite examples of how to look at this area is actually kind of a mundane one. In the 1830s, if you wanted to travel from New York to San Francisco, the price was \$1,400; it took six months, and it was rather dangerous. A hundred and eighty years later, the price is actually less than that, it takes about six hours, and it's quite safe. So what's the difference in travel? It's technological innovation, and the same thing is happening in health care. We have a situation where traditionally medicine has been fairly descriptive and, as I said, it's really been focused on treating diseases rather than preventing them. It's viewed populations as homogeneous, even though obviously that's far from the case. And as I said, medicine has tended to detect diseases, just by lack of technology, at a relatively late stage. So really I think what Arrayit is doing is writing a new chapter in health care that's going to control costs, provide greater accessibility and improve the quality of health care. And the centerpiece of that are these magical devices that we refer to as microarrays, which really represent the technological innovations that we are bringing to the health care

market. With these sophisticated devices, because they enable the detection of vanishingly small quantities of proteins in the blood stream, we can detect diseases many years in advance of the patient actually suffering from disease symptoms; in ovarian cancer, probably five years before serious symptoms appear. In the case of neurological disorders, such as Parkinson's disease and Alzheimer's, perhaps as much as 25 years in advance of having any disease symptoms. Obviously, what that affords is a number of things. It greatly improves treatment options. The other thing that it does is it gives us some time to actually design new therapies, whether those therapies involve the use of small molecules, pharmaceutical compounds, drugs, stem cell therapies or other types of therapies. It also identifies the key targets and pathways that again allow us to think about actually treating and perhaps even curing the disease for the lifetime of the patient. That's really what Arrayit Corporation is all about: bringing high technology to bear in health care to prevent, treat and cure human disease. And it's certainly our goal to develop tests, treatments, preventions and cures for all of the major human diseases within the next, say, five to 10 years, and hopefully sooner than that. So we are very aggressively taking on human disease, and we believe, as I mentioned, that technological innovation and particularly the Arrayit platform — because of its versatility, affordability and ease of manufacture among other attributes — is really positioning the company to be a very significant player in this life sciences-driven health care space.

TWST: If it's easy to manufacture, what are the risks in terms of defending the company's position?

Ms. Schena: I think we've positioned ourselves quite well, just from having a unique technology for the manufacturing. So our contact printing technology does differentiate us in the marketplace.

TWST: No one else is doing what you are doing?

Ms. Schena: No, it is a patented process and we control that.

TWST: Is there anything else investors should know about your company?

Ms. Schena: Hopefully, they know our ticker symbol is ARYC and we're on the Bulletin Board.

TWST: Thank you. (SGD)

RENE SCHENA

CEO, Chairman & Director

DR. MARK SCHENA

President, Chief Science Officer & Director

Arrayit Corporation

524 East Weddell Drive

Sunnyvale, CA 94089

(408) 744-1331

(408) 744-1711

www.arrayit.com

Cleveland BioLabs, Inc. (CBLI)



DR. MICHAEL FONSTEIN, Ph.D., has served as Cleveland BioLabs' Chief Executive Officer and President since the company's inception in June 2003. He served as Director of the DNA Sequencing Center at the University of Chicago from its creation in 1994 to 1998, when he left to found Integrated Genomics, Inc., located in Chicago. He served as CEO and President of Integrated Genomics from 1997 to 2003. Dr. Fonstein has won several business awards, including the Incubator of the Year Award from the Association of University Related Research Parks. He was also the winner of a coveted KPMG Illinois High Tech Award.

SECTOR — HEALTH SERVICES

(ANM600) TWST: You have two families of drugs, correct? One is Curaxins, anti-cancer drugs that don't use chemotherapy?

Dr. Fonstein: Yes.

TWST: The others are Protectans, which are designed to keep healthy cells protected from radiation and chemotherapy. It's that family of drugs that can be used by the government in the event of a radiation attack, right?

Dr. Fonstein: Yes, that is what we are developing as a defense antidote, yes.

TWST: What therapies are currently available in these areas besides yours? How will your drugs improve on them?

Dr. Fonstein: In radiation, there are no similar drugs to deal with acute radiation syndrome (ARS). There are basically drugs like iodide, which substitutes for radioactive iodide in your thyroid gland; it's important for children who got radiation damage through contamination of their bodies. But if you are, let's say, hit by an electromagnetic pulse or by a radiation pulse, iodide is no more helpful than table salt. So there is really nothing there except us.

TWST: You've had a distinguished career as a scientist. Why did you become an entrepreneur?

Dr. Fonstein: It was more or less by accident. I was an Assistant Professor at the University of Chicago, and I was studying genomics. Then it became obvious to me that genomics is becoming an industry. And if you want to develop industrial approaches, academia is not the best place. So I started my first company with two people and then built it to 150, and that's how it started.

TWST: What was the name of that company?

Dr. Fonstein: Integrated Genomics, and it's still around.

TWST: You started your current company in 2003, in Cleveland, correct? It was a spin-off of Cleveland Clinic.

Dr. Fonstein: Cleveland Clinic is one of the biggest clinics in the U.S., with a turnaround in the low billions. That's quite a big clinic. It's a huge corporate entity, and that's the place where the science came from in the form of a friend of mine, a distinguished professor, Andrei Gudkov. Basically, we licensed some of his developments and Andrei Gudkov himself to the company. And that's how we worked.

TWST: Why are you headquartered in Buffalo? Is that because of your association with Roswell Park?

Dr. Fonstein: Yes, that's the oldest cancer center in the U.S. While we were enjoying the collaboration with Cleveland Clinic, we needed a place which would be a committed test ground in the cancer area. Cleveland Clinic has a cancer department that's quite sizable, but a corporate alignment was impossible. And for us it would be like dancing with an elephant. So with Roswell Park, the order of magnitude is more in line.

TWST: When you went public in 2006 was it a fairly small offering?

Dr. Fonstein: Yes, it was a small offering, but there were several reasons to do this and it was quite an opportunistic development. This way we can raise money easier and cheaper than other ways. It was also clear that we would be dealing with the government. And the fact that you are a public company which must disclose all your financials and other things is helpful when you're dealing with the government. So basically, you go through the hassle of being a public company, but at least you have more than one reason to do so.

TWST: Would it have made more sense to find angel investors or private equity?

Dr. Fonstein: No, angels are mostly in heaven. They have sightings, but they are like UFOs. Doing the venture capital route was a possible alternative. But my view on VC money — they sell you expertise, and that's why their money is very expensive. If you are a professor of a university with limited business experience, then it is absolutely the right thing for you to do. But by then I already had five years in business, so basically I didn't need somebody to explain to me how to run a business. And we were already networking with pharmaceutical firms.

TWST: You have quite a bit of experience, and you're still young.

Dr. Fonstein: Yes, I just turned 50 a few months ago.

TWST: What's the role of the Armed Forces Radiology Research Institute?

Dr. Fonstein: They are good allies, and they are one of the few places which study radiation in a very applied manner.

There are only two places in the U.S. — and maybe there is another place in France — which are seriously studying the effects of radiation on anything but mice.

TWST: So it's a very limited area, but a very critical one because, as we've been told, a radiation attack in New York City would cause unimaginable damage.

Dr. Fonstein: I mean, if you look at the order of threat, I think it is considered to be the number one threat.

TWST: You've had a bumpy ride in the market. Do you watch the stock price constantly?

Dr. Fonstein: Unfortunately, I do. You have to be superhuman not to. On the other hand, I should not because we believe that by the end of this year, we'll be finalizing preparation of our submission for FDA licensure. At that moment, our stock will probably be defined not by sentiments of the marketplace but by economics of the field. We can become a company that is really selling products.

TWST: So real sales that investors can see.

Dr. Fonstein: Instead of measuring the promises.

TWST: In your literature, you say your drugs are at a critical inflection point. What does that mean?

Dr. Fonstein: We have demonstrated an exceedingly detailed efficacy of the drug in animal models. We demonstrated basic tolerance of the drug in humans in our initial safety study. So for the next year or slightly less than that, we need to do more of the same in order to have the drug approved. We had a meeting with the FDA, which gave us a lot of detailed instructions how they would like to see it be done. They helped us to zoom in on the target instead of just guessing what they would like.

TWST: One thing drug companies have always complained about is the FDA. But you say meeting with the FDA gave you clarification on a lot of things?

Dr. Fonstein: I have to say that so far all of our interactions were very fruitful. And if there were demands or requests, they were all very logical. While we don't have approved drugs yet, I really found them very helpful. I think the difference is we're bringing a novel treatment for a clearly unmet medical need.

TWST: In practical terms, many small drug companies have said they'd require a big partner like a major pharmaceutical firm to go through the FDA.

Dr. Fonstein: In a general sense, it's absolutely true, but not always. The reason why you need a partner is that after you get Phase III approval, you need to be able to sell your drug. But in our situation, our flagship products will be an antidote for radiation and will be used for national defense. So we don't need companies like Pfizer. We already have an important partner — it's the U.S. government.

TWST: In firms like yours, selling as opposed to product development has always been the challenge. Your staff and board are loaded with Ph.D.'s and very smart people; but for other products, where is the marketing talent?

Dr. Fonstein: There are two types of things we are planning to sell. One is a defense antidote. We have very, very strong people working in collaboration with us, and we have some people on the team in the company as well as consultants. In terms of

medical products, I think it's just too early for us. We are just starting first human trials. We are about to start head and neck cancer trials, and radiation protection. So marketing those things are two years away.

TWST: That's two or three years away for the other drugs, such as Curaxin. But the Protectans are very close because I see in November you opened the second human study, right?

Dr. Fonstein: Yes, this is for the defense product.

TWST: So Protectans are the first prong of your thrust, correct? Will the second prong be the Curaxins? Do you have this aspect basically funded?

Dr. Fonstein: We have Curaxins completely funded for at least three years in order to bring them to conclusive Phase II trials. After a conclusive Phase II, we will start looking for next-level partners.

TWST: So that's when you may have to look for the big pockets. But that's a couple years away, right?

Dr. Fonstein: By then we may become a big pocket ourselves. If our defense product will be as efficient and economically effective as we think it will be, then we may be a big pocket ourselves, or we will decide whether it's a good idea to look for a partner. At least we have this option.

TWST: How many do you have on staff and how many are scientists?

Dr. Fonstein: Right now the company has 32 people. We have a few bureaucrats but are mostly scientists. We have a team of roughly 10 people who are drug developers.

TWST: How many patents have you been awarded?

Dr. Fonstein: We just received our first patent. We have about 16 sets of applications at various stages of consideration in the U.S. and abroad. We have just received the first key U.S. patent for our lead compound. U.S. patenting is somewhat slower than Australia or some other places.

TWST: Anything final you would like to say about your company?

Dr. Fonstein: I think there are several things which make our company different from many other biotech companies, and I mean different in a good way. One thing is that our products are based on very deep scientific background. Second, a lot of our funding is coming from government sources. In fact, we raised about \$50 million from public markets and about \$50 million from government sources, so it's dollar for dollar. Investors should also feel pretty happy about the fact that our lead product, CBLB502, is about a year from submission for approval. When this happens, we will be selling.

TWST: Thank you. (EJL)

DR. MICHAEL FONSTEIN
 CEO & President
 Cleveland BioLabs, Inc.
 73 High Street
 Buffalo, NY 14203
 (716) 849-6810
 (716) 849-6820 — FAX
 www.cbiolabs.com