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THE WALL STREET TRANSCRIPT

08-05-13

MEDICAL DEVICES REPORT

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Founded 1963
Published by Wall Street Transcript Corporation
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ANALYST INTERVIEW

CHRIS COOLEY — STEPHENS INC.

CHRIS COOLEY, who has over 18 years of equity research experience, joined Stephens Inc. in July 2010 as a Managing Director focusing on the medical device and hospital supply sector. He was recently ranked number for stock selection by The Wall Street Journal All-Star Analyst Survey as well as StarMine/Financial Times in 2011, and was ranked number one for stock selection by both The Wall Street Journal All-Star Analyst Survey and by StarMine/Financial Times for his work in the sector during 2009. Prior to his employ with Stephens Inc., Mr. Cooley began his professional career with Dean Witter, and also worked for Cargill, Inc.; Morgan Keegan & Company, Inc.; SunTrust Equitable Securities and FTN Equity Capital Markets. Mr. Cooley received an MBA with concentrations in finance and operations management from the University of Tennessee and a B.S. in economics from the University of Arkansas.

SECTOR — HEALTH SERVICES

(AEN802) TWST: What is going on in the medical device space from a business perspective at this point?

Mr. Cooley: I think we’ve seen quite a bit of change, or potential change, over the course of the last two years. And what we’re seeing now within the industry is I think players settling in, if you will, and moving forward under what we now have with the Affordable Care Act and a little bit more strenuous FDA environment. And basically what that means is that medical device manufacturers I think are increasingly focusing on truly step-function-type changes that can demonstrate not only improved clinical benefits but also some material cost savings.

I also think what’s really unique to our industry that we haven’t really seen over the last 15 to 20 years is, we are increasingly seeing medical device manufacturers take their technologies abroad and effectively design them for the international markets first and then subsequently look to commercializing those devices here in the States.

TWST: What’s caused that change? Why look overseas?

Mr. Cooley: I really think it’s a function of two key points. The first being uncertainty on the regulatory front and specifically looking at what the U.S. Food and Drug Administration, or the FDA, requires in terms of getting a product approved now under the old 510(k) or PMA pathways, and then secondly it’s reimbursement. We are increasingly not seeing more favorable reimbursement for new technologies coming into the space at a premium, so where you are thinking about higher upfront development costs and subject reimbursement, manufacturers are increasingly moving abroad where they have a faster pathway, especially in Europe through the CE mark process and a defined reimbursement rate. It is just easier to define the return.

TWST: Can you get the same margins overseas as you can in the U.S.?

Mr. Cooley: That’s a great point that you raised. Historically, we’ve always thought about the international markets as being lower margin or lower contribution versus the opportunities here in the States. But when we consider the very costly and potentially lengthy
TWST: So that’s a real change?
Mr. Cooley: That’s a sea change.
TWST: You mentioned the business has slowed a bit. Is that mainly due to the economy?
Mr. Cooley: I think it’s, again, multifactorial. I think one of the key drivers here has been employment, and also the other key area there has been demographics. And if we think about it, if you aren’t employed, insurance maybe subject, and so elective procedures in particular have taken a hit, if you look at it over the last four years. If you have to have a hip replaced, or alternatively you have to have a stent implanted, those type procedures we don’t necessarily see the reduction in volume. But on the elective side, definitely have seen a curtailment of procedure volumes. Similarly, if we think about it from the perspective of reimbursement, in particular in the spine space, you had a number of reimbursement pressures there on fusions, and that’s served to quite frankly curtail volumes.

TWST: Why particularly in the spine space?
Mr. Cooley: Spine was under pressure really over the last three years, but we started to see stabilization there now on reimbursement, and it just gets back to data on the efficacy of fusions in terms of both improving pain but also range of motion. Quite frankly, there has been some mixed results with some of the technologies out there.

TWST: You also mentioned the impact of the FDA. Why have they become tougher in the space, where historically approvals weren’t very difficult to get?
Mr. Cooley: I think the pendulum swings back and forth in this space over time. And it’s — I don’t want to represent the FDA as an impasse. I mean, they have to basically walk a very fine line between rushing to get new technologies into the marketplace, which could potentially benefit patients, while also having a very difficult job of basically being the watchdog, if you will — preventing things from getting into the marketplace before they are ready and possibly causing harm. But I think it’s with the balance of trying to increasingly focus on mitigating risk, which we can never totally eliminate. We’ve seen a much more lengthy process in particular within the agency.

TWST: Has that added significantly to the cost of bringing product to market?
Mr. Cooley: It has, it has.
TWST: Is there any sign that it’s going to get easier again, or is this something everybody’s got to live with?
Mr. Cooley: I struggle between if this is the new normal or if we are actually going to see some improvement. From a conservative standpoint, I’d say this is the new normal. But we have seen, in terms of some of the prefiling work, that many med device companies now have increased interaction on the front end before they actually have their formal filing, initial filing with the agency. We are getting better. And so what you are seeing are submissions which fit the bill, if you will, for what the agency is looking for, and when we look at the timelines as a result of that for approvals, we are seeing some improvement when you look at the actual filing date to actual approval. But what that doesn’t take into consideration is a more lengthy process now on the front end in terms of that lengthy informal dialogue that they have with the agency before the formal filing submission takes place.

TWST: So in that case, the industry is learning what they think the FDA wants?
Mr. Cooley: I think that’s a great summation. The medical device industry in this country and abroad I think is incredibly resilient and has had to adapt on a number of fronts through the years, and they are doing that once again, and I think doing that successfully.

TWST: We are facing the new Obamacare. What does that mean for the space?
Mr. Cooley: Quite frankly, I think it’s a little bit of a headwind. Medical device manufacturers will obviously have to pay the tax, and that’s a tax on revenue, not profitability. So while we think about it as 2.3% on sales, it’s actually a much greater impact when you think about how it flows through to the bottom of the P&L. They will try to get some of that back I am sure in the end markets, but in this day and age, that’s just increasingly difficult.

The offset was supposed to be increased volumes, but I don’t believe that we’ve met with any device industry representatives, or quite frankly from our own work, we don’t believe that you are necessarily going to see a significant influx in terms of patient volumes. I think what you are really seeing is a shift at the payer level in terms of the reimbursement mix as opposed to incremental volume coming back in basically to offset that 2.3% of the total top line. It’s clearly a burden on the industry, and I think the biggest burden unfortunately falls on the smaller companies, which historically have been the hallmark of innovation in our space. It’s,
TWST: How about from the aspect of pressure on reimbursement under this new approach?

Mr. Cooley: We are still trying to figure out what the new approach is in totality. The exchanges are now getting pushed out; it looks like we are going to be little bit late in implementing this. I don’t think that’s going to come as much of a surprise, but over time I think you will continue to have to see further pressure from a reimbursement standpoint. That we don’t anticipate to abate, and that’s why as I mentioned at the outset device manufacturers — it’s not enough just to have an incremental improvement within an existing device category. You really need to show demonstrable benefit to the patient in terms of clinical outcomes, or address something that quite frankly hadn’t been addressed in the past successfully to obtain reimbursement. It’s harder to maintain that margin today than it ever has been in the past.

TWST: In this brave new world, are we going to see consolidation because you have to be big?

Mr. Cooley: It definitely seems to make sense. Scale really matters in this industry when you think about it from a global reach, the material cost to develop a new device from start to finish. But on top of that, a number of medical device companies are relatively replete with cash. Interest rates, as we know, are extremely low. And with an uncertain timeline in terms of what it really takes in terms of timing and capital to get a new device through the FDA and then to commercialize it in the States, I think we are increasingly seeing kind of a model change, where you have the larger strategics make earlier-stage investments in private companies or startups.

“With an uncertain timeline in terms of what it really takes in terms of timing and capital to get a new device through the FDA and then to commercialize it in the States, I think we are increasingly seeing kind of a model change, where you have the larger strategics make earlier-stage investments in private companies or startups.”

TWST: When you look at the industry, where are the new opportunities? Are there new spaces or devices that are coming down the road that look attractive?

Mr. Cooley: I definitely think there are. We have seen some exciting developments in diabetes care with further advancement in sensor technology in public companies like Dexcom (DXCM). Private companies like Tandem Diabetes Care have made insulin pump usage far more user friendly, and quite frankly dispensing the insulin more efficiently through a siphoning system. We’ve seen some tremendous innovation in the ophthalmic industry as a whole in terms of new lens-based technologies for cataract patients and those that want to undergo a refractive option from a lens-based modality. And we are clearly seeing, as always, in the cardic space great innovation there as well. One company that comes to mind is Endologix (ELGX) — two new devices, one the Nellix system, the other Ventana, both of which really stand to expand the market for endovascular grafts treating abdominal aortic anerysms, or AAA. There’s always going to be innovation here in the space.

TWST: So there is no lack of new product coming to market despite the changes?

Mr. Cooley: Correct. The medical device industry is all about innovation, and that’s continuing. I just think it emphasizes the need for that innovation going forward as against things that just really don’t add value.

TWST: Earlier on you mentioned the higher costs of bringing product to market. Does the industry have the balance sheet to support that?

Mr. Cooley: I definitely think that you see the larger conglomerates with that type of capital structure. But what I think we are again seeing is a little bit of a change where those companies don’t want to invest truly directly; they will have partnerships with some of these smaller companies. Similarly, some of those smaller public companies, though, have had to come back to the markets here in this a little bit more favorable market we’ve had here so far in 2013, to kind of top off the tank so that they can have enough just in case the process becomes much more lengthy.

TWST: Has the market been receptive?

Mr. Cooley: To date they have in the names that we’ve seen and monitored closely. I think it’s almost expected by some investors that just, again, more costly to go from concept to commercialization than it ever has been before.

TWST: What’s the interest level of investors in the space at this point?

Mr. Cooley: Fortunately, as I have a vested interest being a med tech analyst, it’s gotten better. I would definitely say in the second half of last year, the med tech industry was in the penalty box for investors. There was just too much uncertainty with Obamacare going in front of the Supreme Court, and then in the second half of the year concerns about the fiscal cliff and what that may or may not mean to Medicare reimbursement rates. But as we have come back into 2013, the industry as a whole has outperformed the S&P quite healthily, and I think it’s a function of the fact that investors realize what this
industry provides is life-saving and life-enhancing technologies, and there really aren’t viable alternatives to these devices.

Historically, these companies have very healthy margins in the mid- to low 20s, and they are all replete with cash at this point in time for the most part, so it’s a good space to be in. We try to focus a little bit more here on the growthier-oriented names, and as we increasingly see these companies going abroad, we can see healthy 10% to 15% growth in a number of companies. So interest has picked back up, and I hope it stays that way.

**TWST:** Makes life more interesting if it does for you.

**Mr. Cooley:** Most definitely.

**TWST:** Where should investors look? Who is on your “buy” list at this point?

**Mr. Cooley:** One of the names that we have emphasized this year is a company called Endologix; ELGX is the ticker. There we have rated “overweight” with the $17 price target.

**TWST:** Where is it today?

**Mr. Cooley:** Today — we are at $15 now, I guess it is right here today. But a classic example here of true innovation, their core product, the AFX — by the way, this company addresses the AAA market exclusively — is basically growing four times the market rate of growth because it’s, again, easier to deliver and has broader applicability with great clinical results.

Their pipeline, though, is the real excitement here, and when we think about it, there is one device, Ventana, which basically has the opportunity to expand the market by upwards of $400 million; it’s about a $2.0 billion to $2.2 billion market today. And then Nellix, which just received a CE mark in Europe, really has the chance to change the game in the way that we think about endovascular approaches versus open surgical repair, and we see a very significant growth trajectory there; core top line growing in excess of 25% over the next three years. Another name that we continue to focus in on —

**TWST:** Staying with that one for a second, how far away from coming to market are these newer products?

**Mr. Cooley:** Sure. In Europe, they are here today. Specifically Nellix began commercialization during the June calendar quarter. We think Ventana will enter the European market in the second half of next year, 2014. For us here in the States, they are further out. These products, realistically assuming standard FDA timeline, will not be available until the end of 2015, early 2016.

**TWST:** OK. What’s the next name?

**Mr. Cooley:** The next name that we like is STAAR Surgical (STAA). It’s in ophthalmology. But the real exciting thing about this business is they have two new products, both of which are available on the market today in the U.S. as well as abroad, servicing the cataract marketplace, which is the largest surgical market in ophthalmology, but also the refractive market with a premium lens option. What’s unique about STAAR is that you are seeing its core product, the Visian ICL, deliver unit growth in excess of 20% right now as the market starts to increasingly adopt lens-based options as opposed to laser or LASIK type choices for refractive surgery.

The lens generates about an 80% margin to the company. They have no debt, generating significant amount of cash, and on the cataract side, they have a premium lens material called COLLAMER, which is exclusive to STAAR, which gives you the benefits of both silicone and acrylic from the surgical side. So you get a premium lens outcome at quite frankly a base market price, and with that, this company is really starting to realize an acceleration in its top line, and its margin structure is improving.

**TWST:** Why the shift from LASIK to lens space?

**Mr. Cooley:** Historically, we’ve had a LASIK market here in the U.S., and LASIK is a great procedure, and many patients can benefit from it. But we’ve also noted that in higher order myopes and patients that have astigmatism, you can get a quality or in most cases better outcome with the Visian ICL. And we are defining better, saying that you hit your target refraction on the first surgery, there are less complications in terms of glare and halo, and less instances of dry eye, and as a result of that, surgeons are increasingly adopting the technology. It also preserves the downstream option for the patient. As we all get older, unfortunately cataracts are just a fact of life, and if you’ve not changed the corneal surface as you’ve done with LASIK, it’s much easier to use one of these new premium multifocal or accommodative lenses as your lens option when your cataract is removed.

**TWST:** So it’s not permanent as LASIK is?

**Mr. Cooley:** No, no. Both of these again are — it could be removed, but both of these are for one-and-done type approach. It just — when you are later on in life and have to have cataracts addressed, it basically puts more options on the table potentially for you.

**TWST:** Is there a third name on your list?

**Mr. Cooley:** One of the names that we’d focus in on plays to the theme of better medicine and reducing costs is NxStage Medical (NXTM). This is a company which is focused on the dialysis
marketplace, and it’s an important market in the sense that it’s only about 2% of the patients — I am sorry, 2% of the Medicare population — when we think about the patients in the U.S. each year. But they account for 8% of the annual Medicare outlay, so a disproportionate amount of costs associated with this patient population.

What NxStage does is they have a proprietary, and they are really one of only two that have what we call a home hemodialysis system. So patients can actually have a fuller, healthier life, have control of their day and do dialysis in the home setting as opposed to having a go in-center three days a week. It’s important in the sense these patients are healthier. Studies have shown they live longer and they use far less medications, but also it saves the system money over time, and as a result providers do better by providing this technology. We think it’s a really interesting story, and it also again plays to better medicine, lower cost.

TWST: And the cost curve is becoming increasingly important, correct?

Mr. Cooley: Sure. Reimbursement for home hemodialysis, or HHD, is readily done right now by private payers. Medicare reimburses as well under a petition for medical necessity. And from the provider standpoint, they can save upwards of maybe 50 bucks per procedure, or I should say per treatment, out of the existing bundle, which is $240 by doing it home for the patient. So you are saving money for the patient, but more importantly the patient is healthier, they are staying out of the hospital and they are living longer.

TWST: So everything kind of works to their benefit?

Mr. Cooley: It’s truly a win-win.

TWST: Any names on the other side of this equation, that you worry about in this space?

Mr. Cooley: I would just say that names that really aren’t doing anything innovative, and as a result of that you are going to be far more susceptible to price pressure on the top line. I also think it’s harder in that situation to basically buy growth today versus, say, three years or four years ago. Kind of along these lines, I’d focus in on capital names, because again, that’s — it’s difficult for a hospital system with an uncertain budget going forward to really make that commitment with an uncertain return in the future.

TWST: Anything else we should touch on?

Mr. Cooley: No, this has been great. I appreciate the opportunity to speak with you today.

TWST: Thank you. (TJM)

Note: Opinions and recommendations are as of 07/11/13.

CHRIS COOLEY
Managing Director
Stephens Inc.
111 Center St.
Little Rock, AR 72201
(501) 377-2000
(501) 377-2470 — FAX
(800) 643-9691 — TOLL FREE
www.stephens.com
RAJ DENHOY joined Jefferies & Company, Inc., in November 2009 as a Senior Equity Research Analyst covering medical technology. Prior to joining Jefferies & Company, Inc., he was a Senior Analyst at Thomas Weisel Partners, Bear Stearns and Piper Jaffray & Co. He has also worked at J.P. Morgan and Banc of America Securities, and has been covering the sector since 1998. Mr. Denhoy holds an MBA from Cornell University, an M.S. from Georgetown University in human physiology, and a B.A. from U.C. Berkeley in biology.

SECTOR — HEALTH SERVICES

(AEN804) TWST: Medical devices is a broad space. Where is your focus?

Mr. Denhoy: Our coverage is in a number of areas, everything from the cardiovascular space to the orthopedic space, to some smaller companies in diabetes and radiation oncology, ophthalmology, some of the more hospital-based product companies. I like to describe it as kind of the waterfront of medical devices.

TWST: What is driving the space at this point, is it ObamaCare or Medicare?

Mr. Denhoy: I think there are several major themes that have been playing out for the last couple of years in medical devices. To really have an understanding of where we are today in this industry, you have to take a historic perspective of where’s it’s been for the last 25 or 30 years. Devices have historically been a really high growth area of health care. For a lot of years there was a tremendous amount of innovation happening, a lot of new markets being opened, a lot of new device categories being created, which spurred a lot growth for the companies in this space. But there were also unique aspects of this sector that helped drive growth, and one important one was that the selector, or the person who decided what type of technology was going to be used, was typically a clinician — a surgeon for the most part — and that person selected the products they used for a lot of reasons that for the most part weren’t related to price of the device. There was very little connection between the selector of the technology and who was paying for it, and that has changed really dramatically in the last couple of years as the incentives have begun to realign.

There has also been a lack of real innovation across big segments of this industry, and the general manifestation of all of it is that a lot of the larger categories in this sector, things like a lot of the cardiovascular categories — pacemakers, defibrillators, stents — and a lot of the orthopedic categories — hips, knees, spine products — and even to a degree some of the hospital-based products have come under increasing pricing pressure. Because there is very little clinical differentiation anywhere between a lot of the products in these categories, these devices have started to behave largely like the commodities that they are. The companies are selling to a different customer, and that tends to be the hospital now, and that entity is much more price-sensitive. So you’re seeing, I think, a lot of those larger categories really grind to much slower growth, and in some cases they’re in decline, and so for a lot of the large companies, they are exposed to a lot of those markets and their results have suffered.

So for the last several years there’s been a slow realization of the new dynamic that these old business models aren’t working, and the big stalwarts of this industry have slowed. And the companies for the last several years have been slowly refining their strategies and how to deal with this new reality, and so you’re seeing quite a bit more
focus on acquisitions to drive growth, to really accelerate growth into new areas. You’re seeing investments in international markets, you’re also seeing a lot more sort of shareholder-friendly activities on the part of these companies in returning cash to shareholders. There is a lot of rhetoric about becoming partners with hospitals and trying to find new ways to deliver technology to customers. But in the end, there has been sea changes taking place over the last couple of years in the business of medical device, and I think, to a great degree, we’re still sort of midstream in all of this, and it’s been a pretty unsettled time for this industry.

TWST: Are we kind of midway through this transition, or are we getting toward the end of it?

Mr. Denhoy: The pressures that are going to be exerted on some of these device categories as pricing bleeds out of them, I think we’re still midstream in that. In terms of the companies’ responses to them, in terms of the adjustments of strategies and the like, I think we’ve seen a pretty big move in that regard. There hasn’t been a lot of payoff yet in terms of accelerating growth or better performance out of these companies, but there has been, I think, a pretty big shift in the way these companies are approaching their markets.

TWST: How about the role of the FDA. Is that also changing the texture?

Mr. Denhoy: I think the FDA is oftentimes kind of demonized by the industry in terms of being the source of a lot of the problems here, but the FDA has a particular role to play, and that’s assuring that the safety and efficacy of devices are upheld. And so to that extent it may be they’re making it a little more difficult for products to get to market, but I don’t think they’re the source of all the problems with this industry. Again, I think in some respects the industry is kind of a victim of its own success in a lot of ways. A lot of device categories are very good, the outcomes of a lot of these have been, I think, a pretty big shift in the way these companies are approaching their markets.

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TWST: As we look out, what kind of growth is the industry capable of generating?

Mr. Denhoy: I think the larger, more mature companies — and here I’m talking about companies like Medtronic (MDT) and Boston (BSX) and St. Jude (STJ). Zimmer (ZMH), Stryker (SYK) to a great degree, even Covidien (COV), names like that — I mean, just given the size of those companies and their relative exposure to a lot of those slow-growth markets, they have to be thought of as low-single-digit-growth kind of businesses, low-to-mid for the most part. But having said that, there are still categories that get created which grow faster, things like transcatheter valves or heart support pumps or some of the insulin delivery and testing devices; so there are still categories that have growth, but they tend to be newer technologies that are underpenetrated. So there still are certainly veins that can be tapped, and people are trying to find that better performance, but it’s getting more difficult to find.

TWST: Are these newer technologies coming out of smaller companies, or are some of the bigger guys playing in the space?

Mr. Denhoy: Mostly it comes from small companies, and we’ve seen a lot of it get acquired by the big companies. As I mentioned, one of the big responses to the slower growth in the sector has been to try and find new engines of growth, and for a lot of these companies that has come through acquisition. They are trying to acquire some of these more interesting technologies with the hopes that over time they’ll get large enough to sort of offset some of that slowing in the larger, more mature segments. It hasn’t happened to a great degree, but I think a lot of the companies have refilled the cupboards, and now it’s just a question of when and if those businesses get large enough over time to offer some better performance.

TWST: Have acquisitions in the space been efficient and effective?

Mr. Denhoy: I think it’s too early to say. I mean, there have been better acquisitions than others certainly, but again, I think the unfortunate reality is that the biggest markets in the industry are things like hips and knees and ICDs and stents. I mean, those are multi-billion-dollar markets, and most of the acquisitions are measured in the tens or hundreds of millions of dollars in terms of the current revenue potential. Some of them aren’t even generating revenue at all right now. So in a sense, they haven’t yet been able to offset a lot of that slowing for a lot of the big companies. I think there is some expectation building that over time we will see some of that, and we have seen some better performance out of some of these stocks of late, but it hasn’t really yet manifested completely in numbers.

TWST: Have the bigger companies been overpaying for these newer technologies?

Mr. Denhoy: Hard to say, but certainly they aren’t shy about paying up for them, because I think another really important facet to understand about this is, despite this view that things are challenging for these companies, they do have the luxury of the change not taking place overnight. I mean, this is kind of a slow process, I think, for these industries; the change is glacial in a sense. The companies are managing through it, and they’ve still been able to maintain very healthy operating profitability and cash flow. So they do have the flexibility right now to do stuff. Things haven’t gotten so bad that they’re without any options, and so their ability to pay for technology is good. Some of these companies generate multiple billions of dollars a year of free cash, and they want to put it to work.

TWST: So it’s a matter of finding the right things?

Mr. Denhoy: Yes, I think that’s been, frankly, the more challenging piece of it, is finding the right types of acquisitions.

TWST: Is there a lot of competition for these acquisitions at this point?

Mr. Denhoy: I think when companies do get to the scale...
where they’re looking to get acquired or where there’s a process from these companies, yes, I think it is fairly competitive, because again, I think a lot of the larger companies, as I described, are all in the same situation. They’re all looking for that next big growth opportunity on the top line. They all still believe that there is growth to be had in this market, and the way they get it is — if they can’t develop it internally — is to acquire it.

TWST: What’s prevented them from doing it internally; is it just that it’s so difficult to come up with good new product?

Mr. Denhoy: No, I think that’s probably a different type of discussion in terms of why large companies have trouble innovating, but it’s kind of a truism that most innovation, again, tends to come from smaller shops.

TWST: As you talk to investors about the space at this juncture, what’s the general attitude? Are they interested?

Mr. Denhoy: It ebbs and flows, certainly. I think as much as it’s been an educational period for the industry over the last several years in sort of adapting to the new realities, new paradigms that they are all operating under, there has also been investor education during that period as well. For several years this sector was very much out of favor, because we didn’t know how bad things were going to get. It was clear change was taking place, but how that was going to manifest and over what period of time was kind of unknown. And so, to ask somebody to get on one of these boats as we’re heading into a storm is kind of difficult to do, but if you have a sense of where they’re going to come out the other side, it makes it a little bit easier. And I think over the last several quarters, perhaps, last year, there has been a better understanding of what’s taking place here, and because things were happening somewhat slowly, still heading in a negative direction, but not overnight, I think there has been an understanding you can still own these stocks, you just have to be careful of not overpaying for them and understanding what the realities of what they’re dealing with are, but there still are opportunities.

So as you’ve seen, a lot of these stocks have done quite well over the last six months or so. Part of that is this is understanding that these businesses may be somewhat challenged, but you’ve got management teams that have come to terms with this, and they’re trying to do all the right things in terms of looking for acquisitions and looking to expand into new markets, looking at managing the size and scale of their businesses, such that they can still return fairly good cash and subsequently dividends and buybacks and things to support these equities through these tough periods.

TWST: There really is somewhat of a changed paradigm?

Mr. Denhoy: For sure, the last several years have been a reassessment of what this industry is and what the outlook is.

TWST: What’s going to be the catalyst to get investors to step up? As you say, they’ve done well over the past six months or so; what’s it going to take to continue that?

Mr. Denhoy: Something we haven’t talked about is the last several years have also seen a slowing in procedure volumes due to the downturn in the economy and from pressure on device utilization from payers. If there is any sort of fundamental change in that equation, patients start to go to the hospitals more or some of the international markets start to improve, Europe in particular, it could be a positive catalyst if the underlying demand equation is improving. If we see some lessening of the pricing pressure that would be, I think, pretty positive for this industry.

TWST: What kind of signs do we look to, to see if that’s happening?

Mr. Denhoy: We all try and do surveys on the things like how often people are going to the doctor’s and hospital admission rates and those sorts of things, but in general it tends to be commentaries from these companies and also from people in the industry, doctors and the like, about whether anything is fundamentally changing on the ground.

TWST: And is that slowdown, is it mainly economic?

Mr. Denhoy: It’s happened on a couple levels. I think the economy has certainly contributed through the recession, but there is also an increased scrutiny on the utilization of a lot of this technology. There are several high-profile journal articles about the overutilization of certain types of technologies — stents, ICDs, spine procedures — and I think some insurance companies and payers took to heart some of the conclusions that these device categories may have been overutilized, and so there has been a higher level of scrutiny on the utilization of this stuff.

TWST: That’s probably going to be around for a while?

Mr. Denhoy: Yes. But that also — you know, at some point you start to anniversary those things. And so that could also be a catalyst, in the sense that we don’t see another step down. Eventually you start to reach another sort of a level of stability.

“A lot of these stocks have done quite well over the last six months or so. Part of that is this is understanding that these businesses may be somewhat challenged, but you’ve got management teams that have come to terms with this.”

TWST: Where should investors be focusing? Is it on cutting-edge technology?

Mr. Denhoy: It depends on what investors are looking for in this industry. If people are looking for steady growth with...
certain challenges, but still decent returns and cash flows, I think the industry broadly offers that. If investors have an appetite for faster growth, more risky kind of stories, there are those as well. So you have a lot of choices in some respects.

We tend to focus more so on growthier names, companies that have interesting technologies that they’re rolling out or launching, so a company like Edwards Lifesciences (EW), which is still early in the U.S. launch of transcatheter heart valves. They’ve had some challenges initially in the building of the markets here in the United States. But I don’t think it has diminished the longer-term potential at all for this technology, and they’ve got a multiyear run ahead of them in that regard. Companies like Insulet (PODD), which makes a little pump for delivery of insulin, are just on the very early stages of developing a pump that also includes a continuous glucose monitor. It will be several years before it gets here, but the potential for that product is enormous for Insulet. So names like that, I think, are quite interesting to look at.

TWST: How about on some of the bigger names, are any of them really undervalued at this point?

Mr. Denhoy: I have a difficult time saying that. The stocks have had a nice move over the last six months or so, and they are trading at multiples now which are much higher than they’ve been over the last several years. But again, that’s a reflection of the outlook that there are certainly challenges, but there are solutions being mustered to those challenges, and I think they’ve reached kind of a level of where investors are comfortable with that. But whether people are willing to pay up for those, pay even higher multiples, that strikes me as a bit of a challenge, and conversely, I don’t know if numbers are going to be that much better than we’re already modeling. So is there upside in the multiple? Perhaps not. And is there upside in numbers? We certainly don’t see it. So to suggest that there is lot of near-term upside in some of those large-cap names, it’s difficult to make that call.

TWST: It sounds like it’s kind of a wait-and-see period on the bigger companies.

Mr. Denhoy: I think we are in this period where, as I was describing early, the challenges are pretty well-known finally. It’s taken a while for a lot of companies to come to terms with the fact that it’s not the same game as it was five years ago. But we are seeing a change in strategy and a change in focus for these companies in order to adapt to that;

As much as we talked about some of the improvements we could see in terms of utilization and maybe pricing stabilizing, if any of that gets worse, and there is reason to believe they could, those stocks could have another leg down.

TWST: Anything else we should touch on?

Mr. Denhoy: One area that a lot of companies have made an increasing focus of their strategy is on emerging markets: China, India, Latin America, Russia to some degree. There’s a lot of demand and potential for a lot of this technology to be utilized in those markets. So everybody is devoting a lot of effort into building out infrastructure in those markets. How sustaining that is long-term, given the challenges in those markets is a question. But at least over the short term that’s an area where there has been a lot of emphasis, and certainly something that people should be paying attention to.

TWST: Has it paid off yet?

Mr. Denhoy: Off a small base, yes. Certainly we’ve seen some pretty good growth out of China in particular. But for a lot of these companies, it’s still just a small part of what they’re doing; it hasn’t really moved the needle enough to offset some of the challenges we’ve been talking about in the United States and Europe, in developed markets. But yes, certainly the growth thus far has been quite good. There are questions on how sustainable it is long-term and how much technology those markets and economies...
can really support, but thus far there have been some good results there. But there’s also risk that some of that technology from some of those emerging markets, the lower-price technology, finds its way into the U.S. markets. Could we see low-cost providers of orthopedic implants or even cardiovascular devices come in and start to exert even more pricing pressure here? That’s a risk worth considering.

TWST: Have we seen any of that happen yet, or is that still out there?

Mr. Denhoy: There has been a lot of talk of it and a lot of consideration of whether the markets would be receptive or open to really extremely lower-price technologies from some of these other countries. My sense thus far is that the markets aren’t there yet. Nobody wants a generic hip or knee implant, but at some point that may be the case.

TWST: Does that all fit in with this medical tourism?

Mr. Denhoy: Well, it kind of does to some extent. I mean, to the extent that you can get these procedures a lot cheaper outside the country, people go there to get them done.

TWST: Thank you. (TJM)

Note: Opinions and recommendations are as of 07/01/13.

RAJ DENHOY
Senior Equity Research Analyst
Jefferies & Company, Inc.
520 Madison Ave.
10th Floor
New York, NY 10022
(212) 284-2300
www.jefferies.com

Please see www.twst.com for disclosures.
Unilife Corporation (UNIS)

ALAN SHORTALL is the Founder, CEO and Executive Director of Unilife Corporation, a U.S.-based medical device and technology company that designs, develops, manufactures and supplies innovative, differentiated delivery systems for injectable drugs and vaccines. Since 2002, Mr. Shortall has led the growth of the company’s products into one of the most diversified portfolios of drug delivery systems, positioning the company to be a global leader in the industry. Mr. Shortall spearheaded the transition of the Australia-founded company into a registered U.S. business listed on the Nasdaq Global Exchange under the symbol UNIS, and it continues to be traded on the Australian Stock Exchange under the symbol UNS. Mr. Shortall is committed to the growth of Unilife Corporation, creating strong shareholder value as well as enhancing and saving the lives of millions worldwide who are at risk from unsafe injection practices. In recognition of his substantial marketing and commercial experience and solid leadership of Unilife Corporation, Mr. Shortall, in 2008, was named to the list of 100 Notable People in the medical device industry by trade magazine Medical Device and Diagnostic Industry, or MD&DI. In January 2010, Mr. Shortall was profiled on the front cover of Drug Delivery Technology magazine.

SECTOR — HEALTH SERVICES

AXD600) TWST: Let’s begin with a brief history of Unilife and an overview of your injectable product technologies.

Mr. Shortall: I founded Unilife in 2002. At that stage, we were a safety syringe technology development company. We grew from there establishing relationships with companies including Sanofi in 2004. We focused heavily on prefilled syringe technology. There is no safety prefilled syringe in the world with an integrated safety mechanism built into the device, so that became our primary focus.

Until 2007, we had been based in Sydney, Australia, and listed only on the Australian Stock Exchange. In 2007, we acquired a company in Central Pennsylvania, which had FDA-registered manufacturing facilities and the operational expertise we wanted to transition from a technology development company into an industrial producer. This is a big step that many companies fail on. So by taking that operational expertise and then moving over to the U.S. in 2008, we were able to become an industrial manufacturer of medical devices. We are now a Nasdaq-listed company, and while our shares also still trade on the ASX, we’re a fully-fledged U.S.-based company.

The issues surrounding moving to USA that others might complain about — the regulatory processes and the stringent rules and regulations and legal processes, Sarbanes-Oxley and Dodd-Frank, etc. — for us, from a medical device perspective, was actually a huge benefit. We embraced those stringent regulations. The USA, through the regulations of agencies such as the FDA, has a reputation for the production and approval of premium, high-quality products, so we embraced those high standards and used it to our advantage.

We had a leased facility when we first moved to Pennsylvania in 2007, but we’ve since bought 35 acres close to York in Pennsylvania and have built a 165,000-square-foot state-of-the-art facility. This was actually designed by an architectural firm that works for most of the major pharmaceutical companies. It was designed specifically to ensure streamlined operations and optimum manufacturing processes. We don’t operate our facility at the level of a typical medical device company; we operate it to the standard of a global pharmaceutical company. That’s very important for us. We recently had two FDA inspectors here on-site for four days, and we got a clean bill of health from them, where they found no minor or major nonconformances and were actually very complimentary of the way we manufacture and run our facility and the expertise that we have in-house. As you probably know, an effective, efficient and robust quality system is a critical element of ensuring regulatory approvals at all times.

TWST: You’ve been quoted as saying that 2013 will be an inflection point for Unilife, the year that revenues begin to improve. Can you give us some insight?

Mr. Shortall: Before I can do that I really need to give you a description of what we do. As I said, we were initially a syringe technology development company. We’ve since grown into something much greater by recognizing opportunities and changes in the global market for injectable drug delivery systems, and being able to put ourselves in a position to capitalize on those changes. That’s what entrepreneurial, visionary companies do. And generally it’s not the incumbent companies within a particular market space that come along and change the market. It’s usually the new, innovative companies that come along, see the changes before they happen and capitalize on them, just like Amazon and Apple have done, and I believe that’s what we’re doing.

What we do is design, develop and manufacture drug delivery systems. We don’t do commodity me-too devices. All of our devices are significant game changers in different areas of injectable...
“Instead of putting the drug in an ampoule or vial and using that to send the drug into the market, we allow customers to supply their drugs to the end user in a ready-to-inject device. It’s time-efficient, it’s financially efficient, and it reduces costs in the health care system.”

Now, what is a drug delivery system? As opposed to a normal medical device, an injectable drug delivery system is where the pharmaceutical companies put the drug into the delivery system and then deliver the drug into the market in the device. The device is both the primary packaging container and the delivery system to inject the drug. And so, instead of putting the drug in an ampoule or vial and using that to send the drug into the market, we allow customers to supply their drugs to the end user in a ready-to-inject device. It’s time-efficient, it’s financially efficient, and it reduces costs in the health care system. It also makes it more convenient for patients to self-inject, and increases patient adherence to a treatment regime, which improves health outcomes.

There is no company in the world that has such a broad portfolio of injectable drug delivery systems as Unilife. This financial year is going to be a very productive one in terms of contracts and business growth. We’ve done all the groundwork to bring things to a stage where we are ready to be a reliable, long-term partner to pharmaceutical customers.

Let me liken it to one other company that redefined an industry — Amazon. Amazon, up until 2008, after being founded I believe in about 1994, had spent approximately $2.4 billion in building out infrastructure and operational capability, and there were many debates about the risk of such a substantial investment. Many people argued that Amazon would never be successful.

Well, come 2009 they turned that corner and are now one of the biggest companies in the world. Why, and what was it that turned it around? What was that inflection point? That inflection point was when they had the infrastructure in place so they could build trust with consumers. It was vital that when a customer provided their credit card details to Amazon, they were completely confident that the goods they ordered would turn up the next day. When they established that trust, the whole thing turned around for them. We are at that same point now, with the infrastructure in place and having established the trust of pharmaceutical customers. I believe that Unilife is now at a similar inflection point as Amazon was in early 2009.

**TWST: Your company is pursuing injectable drug delivery systems, targeting pharmaceutical companies as opposed to hospitals and nursing facilities. Are you going to stick with that strategy?**

**Mr. Shortall:** Absolutely, it’s a great model for us because as I say, we’ve out-innovated the competition. The whole market is shifting, and I believe that in 10 or 15 years, the current business model for medical device companies, which is high-volume commodity devices like widgets with low margins, will practically become redundant. It will exist, but in a much smaller size or quantum than it currently does. The market is shifting towards injectable drug delivery systems, and that’s why we’re the leader in that area now.

**TWST: Bring us up to date on your EZMix dual-chamber syringe. What kind of market is available?**

**Mr. Shortall:** Sure, I can explain to you why EZMix is going to play a significant role in shifting the market. There are two major shifts in the global markets that are working in our favor. The first shift is to patients self-injecting drugs. Why is that shift happening? Because patient self-injection significantly helps reduce health care costs, it reduces the pressure on the health care system and then also enhances the lifestyle of the patient.

In 2012, Ernst & Young put out an in-depth research report on the future of health care, and they forecasted that in 10 years, 50% of all health care, not just injectable health care, but 50% of all healthcare will be administered outside of the health care facility and outside of the doctor’s office. So where is it going to happen? It’s going to happen in what is now referred to as the “third place.” That third place is wherever the patient is, whether it’s in their office, in their home, in the gym, in Starbucks, in the movie theater or anywhere else. In order to be able to accommodate that type of future for health care, companies need to provide customization, convenience and safety to the patient.

Then there is the second shift taking place, toward biologic drugs. Traditional chemical-based — small molecule — drugs are created simply by putting ingredients together and creating the drug. It’s why generic companies can replicate them pretty easily. Biologics are actually built on living organisms; they’re incredibly complex. Often times there are 50,000 or 100,000 atoms, and in fact, if a pharmaceutical company was to change a molecular structure in them, they can in some cases become dangerous. So in over 90% of the cases, the only way biologic drugs can be introduced to the body is through injection, so injection as a route of delivery is actually more important now than ever, and will continue to be for the next 20 to 25 years.

These biologics are highly complex, which means that they’re often very viscous, so the challenge is how to get a patient to self-administer a liquid that may be as thick as honey, and to inject it through a very narrow bore needle to reduce the “ouch” factor and make it easy for them. That’s a challenge. We are working with many pharmaceutical companies to help them commercialize some of these complex biologics.

Now to put this into context, there are over 1,000 biologic drugs coming through the R&D pipeline from U.S. pharmaceutical companies alone. These are very high-performance and very high-value drugs, oftentimes selling for anywhere from $2,000 to up to $8,000 or more per dose. The pharmaceutical companies love them, because they don’t have to sell many to have a blockbuster, which is over $1 billion a year. It’s also more difficult when they go off-patent for a bio-similar company to try to replicate them without having to do clinical trials, so there’s a lot of value in biologics for...
pharmaceutical companies. Those which ultimately get approved will have cost an average of $1 billion to get to market, but with so many coming through the pipeline, it’s reasonable to assume, as they’re chasing similar disease states, chronic disease in particular, they’re going to end up entering into competitive market spaces.

“*When the pharmaceutical companies commit to using our devices, they need to protect their supply chain going forward. They do so by locking us into supply agreements that guarantees continuity of supply for them.*”

With more patients self-injecting, the injectable drug delivery system becomes very important as a differentiator and also as an enabler for delivery, so you look out five, six years when a physician goes to write a prescription, then the physician might have a choice of three or four high-performance biologics. With all other things being equal, chances are the physician will write the prescription for the drug that’s the easiest, safest and most convenient for the patient to just self-inject — not only just for convenience, but because the patient’s adherence or nonadherence to a drug regimen can become a big cost to the health care system. So the easier it is for the patient to use it, the better the chances are that the patient is going to continue on that drug regimen.

Now this is where the EZMix comes into play. Over a third of the biologics are expected to be delivered into the market in what’s known as a lyophilized format. That’s like a dry or powdered drug. There are many reasons for that, but the main reason is because of the complexity of the biologics. The pharmaceutical companies are challenged in being able to keep them in a liquid-stable state to meet the shelf-life requirement, so what they’ll do is dry-freeze the liquid into a powder format that has to then be reconstituted with diluent at the time of injection.

Currently, the only real way to reconstitute a lyophilized drug is through a complex process consisting of around 14 or more steps, where the user has to draw up the liquid, inject it into the vial with the powder, shake it up, use another syringe to draw up to inject, etc. It’s a long process, and it’s also a process that’s prone to patient error. If a patient makes an error in reconstitution, they may reconstitute the drug through fluid mechanics, mixing the diluent and the powder together, and then when the patient injects, they have built-in safety with automatic and controlled needle retraction, so when the syringe is taken away from the body the needle has disappeared. There is no risk of needlestick injuries. We’ve been able to take a very complex process down to a very simple one-step process.

You will never give an EZMix or a Unifill to a health care worker or a doctor, or even a pharmaceutical company executive, and fail to receive a very enthusiastic “wow.” The EZMix is a device which can actually enable commercialization of a complex biologic.

One senior executive at a top global pharmaceutical company, for example, recently said upon seeing the EZMix, “For the first time ever, I now know I’m going to be able to commercialize one of the biologics that I’m working with.”

In our business model, you are talking about seven, 10 or 15-year contracts. That’s because our devices are so unique and differentiated. When the pharmaceutical companies commit to using our devices, they need to protect their supply chain going forward. They do so by locking us into supply agreements that guarantees continuity of supply for them. The benefit for us is that we get these long-term supply contracts. And we’re targeting blended operating margins north of 40%, because our sales and marketing expense is practically zero. It’s a business-to-business model. So it becomes a very attractive revenue and profit-generating business model when one looks at those locked-in, long-term supply agreements, many of them being the largest companies in the world — so we’re never going to have any bad debts, either.

**TWST:** Give us some background into the science behind your wearable injector platform. Are there companies doing similar work to what you’re doing here?

**Mr. Shortall:** It is estimated that nearly a third of the biologic drugs coming to the pipeline will end up being delivered in a bolus or wearable injector. As more and more patients are self-administering complex drugs, neither health care workers, doctors or pharmaceutical companies want patients self-injecting into the vein, because it’s too dangerous. They only want patients self-injecting into the subcutaneous tissue in the stomach or abdomen, because it’s safer, less painful and easier for the patients to administer.

Due to the complexity and large molecules in the biologics, as I say, a third of them have to be diluted, so if they’ve got a biologic that’s like Jell-O, they’ve got to turn it into liquid before it can be injected. So what’s happening is, by the time they dilute them, they’re ending up with large dose volumes — 3ml, 5ml, 7ml, 10ml, and 15ml in some cases. Now, the maximum absorption for subcutaneous tissue is 1ml in a standard handheld injection with a prefilled syringe or an auto-injector. The liquid will just ooze out if someone tries to inject more than 1ml. So how does a patient self-inject 3ml, 5ml, 7ml, 10ml or more? They put it into a wearable pump that injects the drug slowly over a period of time. Now, not many people know what a wearable injector is, but with the shift taking place in the market and the advancement of so many biologics, I believe that in about 10 or 15 years everyone will be very familiar with this method of administering drugs. In fact, we’ll all either be using them ourselves or at least will know someone — a friend or family member — who is.

I believe that Unilife has taken the lead in this arena; we are the best in the business for disposable injector pumps. We have an injector division leadership team where we’ve put the best of the best together. We have developed patented technology, which
actually simplifies the process for pharmaceutical companies and simplifies the process for users, and pretty much removes the risk from the regulatory process in the interaction between the drug and the materials, so it’s easier for the pharmaceutical companies to commercialize and it’s also cost-competitive.

“Most of the pharmaceutical companies have several molecules that they’ll require wearable injectors for, so they’re doing extensive due diligence now, because they only want a single platform and single supplier for all their molecules.”

Now, I know of several cases where pharmaceutical companies have completed full evaluations on our wearable injectors against the competition. In every single case we won, and I would say to the market: Watch the space, because you’re going to see those deals coming home over the coming months. I believe those upcoming deals have a significant opportunity to generate revenue for us, because when the pharmaceutical companies sign with us, we will provide them with GMP product over a year or two for them to use in their drug’s clinical trials.

These are typically late-stage drugs that we’re working with these pharmaceutical companies on. Most of the pharmaceutical companies have several molecules that they’ll require wearable injectors for, so they’re doing extensive due diligence now, because they only want a single platform and single supplier for all their molecules. They don’t want to constantly be changing their setups, so they need to determine now that they’ve got the best system. We are providing them with the best product and the best expertise to ensure that they are making the right decision. Once they do their clinical trials, they will actually get approval for the molecule and the wearable injector combined, so in effect they are potentially locked in to the supply of our wearable injectors for the life of that molecule.

TWST: Give us a sense of your I.P. strength.

Mr. Shortall: I would just again stress on the wearable injectors. The major pharmaceutical companies will probably be buying 20 million or so units each — I’m talking about peak volumes in say, five, six, seven years from now for potentially hundreds of millions of dollars in revenue per customer. We’ve got several such opportunities in process. You look at the numbers and targeted blended operating margins north of 40%, and our current market cap is about $250 million. But then to come back to the I.P. portfolio, with the six platforms we have with multiple products in each, and you see the opportunity of generating significant revenues with each of those products. You also look at the long-term supply agreements in 10 or 15 years each, and we’ve got over 84 granted patents, and we’ve got over 200 patents in the pipeline for significantly differentiated game-changing devices. So I could make a very strong case as to why our patent portfolio is worth multiple times what our current market cap is.

TWST: What role will strategic opportunities continue to play between Unilife and the pharma industry? Do you feel there are acquisition or merger candidates out there? Do you feel that your company as it evolves becomes a potential target?

Mr. Shortall: We have made the decision to innovate and out-innovate our competition, and that’s what we’ve done; we’ve done it all in-house, and we’ve got the people and the expertise to continue to do that. We see innovation and our I.P. as our future; it’s our lifeblood. Over 50% of our current burn actually goes into product development, but that is about building value for our shareholders. We don’t look outside in terms of acquisitions, in terms of growth or otherwise. If there was something identified that was going to fit into our very clear business model, and we have a very clear vision of what that is, we would give it consideration, but we don’t want to get distracted. And in fact, we’ve got so many deals in the pipeline now for our current products that we’ve got to be very focused and not get distracted in what we’re doing.

In terms of us being an acquisition target, yes, I think so many companies have actually missed that opportunity. But the value for our shareholders is not in selling out to anybody. The value for our shareholders very clearly is building the value internally. I believe that there’s a significant hyper-growth opportunity over the next four or five years as we bring these deals home with these pharmaceutical companies, and I think the market will actually get a big surprise in terms of what the real quantum of the opportunity is.

TWST: Looking at current management and your internal operations, are there any planned changes or adjustments in these areas?

Mr. Shortall: We continue to grow and bring in top-level expertise. We are at a stage now where the sentiment in the general marketplace, in both the pharmaceutical and medical device industries, is that a lot of key players realize that we are an emerging leader in the field, particularly in injectable drug delivery systems, which is where the future is. So we’re attracting some of the best talent in the world. We are continuously growing, and we’ve now got about 150 people. I think we will probably employ another 40 people over and above that in the next five months or so.

We’re a very high-performance organization. We move rapidly. We are here to serve our customers, and that’s a philosophy that we have within the company. We’re not hierarchical. We actually provide our management and our team members the opportunity to be as great as they can be, so we’re nimble. We move at the speed of light, and that’s what surprises our pharmaceutical customers. We respond incredibly fast with a level of expertise that is generally unheard of in the industry. Because we’re a high-performance team, we constantly look at adding more key players to make us even stronger.

TWST: You’re the founder of this company. What were the challenges and the opportunities that you saw? Have you met the goals that you set for yourself?

Mr. Shortall: I will probably never meet all of the goals I set for myself, but in general principle, I’m certainly on track to outperform what my original expectations were, and I think, if anything, that’s more due to a certain sense of innocence over anything else. That’s because I didn’t originally realize the obstacles that stood in our way. But having now addressed the shifts in the injectable drug delivery market, as I said, to biologics and patients self-injecting with very unique technologies, these were the ingredients for success. Having
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now been able to attract the talent we have to the company, we’ve been able to capitalize on those opportunities.

TWST: As you speak with your own investors, with potential shareholders, industry analysts, do you come up against any misperceptions?

Mr. Shortall: I would think there are a couple of misperceptions, and the first one is, oftentimes they think, “Oh, it’s just another syringe company.” And then they think, “Oh, how is a company like this going to compete with the big medical device companies?” We are not competing with them. We’ve carved out a whole new industry, and it’s our expertise and innovation that’s allowed us to do that. So that’s a major misconception. In fact, where people have said to me often over the last five or six years — how are you going to compete with these big medical device companies — in six or seven years, I believe people will turn around and say, “How are these big medical device companies going to catch up with Unilife?” Because we are literally carving out a new industry; we are writing a whole new rule book for the industry.

And another misconception would be that some people look at our company and say, “Oh, the prerevenue and high burn rate is problematic.” We’ve invested in our infrastructure, where we are now about to bring that value home for our shareholders. We are pretty much prerevenue now. I expect that’s going to change going into the 2014 financial year, and what I think people fail to understand is that over 50% of our burn rate is invested in our product development, which is building our patent portfolio, so in fact, it’s building value for our shareholders. That’s my job, to build value for the shareholders. The capital markets haven’t yet realized the reality of what we have done and what we are doing, but I believe they’ll start to wake up before the end of this calendar year.

TWST: Summarizing your strategic priority for the remainder of 2013 through 2014, what’s on top of the list?

Mr. Shortall: Bring home the deals. There’s no question, top of the list is bring home the deals, and we’re very close to bringing home some significant ones, which I believe will change the dynamics of how the capital market sees us. I mean, we have a number of company-making deals in process, which I’m very confident that we’ll progressively bring home over the next six months.

TWST: In conclusion, why should an investor buy Unilife stock today?

Mr. Shortall: Because of the top-tier quality of the management and expertise we’ve attracted, because of the game-changing technologies that we have developed, because of the significant value of our patent portfolio and because of our business model, which is business-to-business only, where we have long-term supply agreements of seven, 10, 15-year supply contracts with some of the biggest companies in the world. And it’s not only the financial opportunity that I’m talking about; it’s the strategic value that the market has missed, because over the next five or six years we will actually become integrated, not just in the $15 billion injectable drug delivery market, but in the $300 billion pharmaceutical industry where many of our devices will actually be approved as drug device combinations and be locked in to the pharmaceutical companies as part of their sales and marketing processes.

In fact, one of the deals we brought home this year for EZMix will generate royalties for Unilife on the sales of drugs by the customer. On top of that, we’ve got multiple other ways of generating revenue. You’ll see customization fees coming in, you’ll see exclusivity fees, you’ll see royalties from sales of drugs, you’ll see sign-up fees and supply agreements, etc. So we’ve got multiple ways of generating revenue, not just on sales of devices.

TWST: Anything you’d like to add?

Mr. Shortall: No, I think that pretty much does it.

TWST: Thank you. (KL)

ALAN SHORTALL
Founder, CEO & Executive Director
Unilife Corporation
250 Cross Farm Lane
York, PA 71406
(717) 384-3400
(717) 384-3401 — FAX
www.unilife.com
Harvard Bioscience, Inc. (HBIO)

DAVID GREEN, President and CEO, has served as Harvard Bioscience, Inc.’s President and a member of the board of directors of the company since March 1996, and as its CEO since June 2013. Prior to joining the company, Mr. Green was a Strategy Consultant with Monitor Company, a strategy consulting company, in Cambridge, Massachusetts, and Johannesburg, South Africa, from June 1991 until September 1995, and a Brand Manager for household products with Unilever PLC, a packaged consumer goods company, in London from September 1985 to February 1989. Mr. Green currently serves on the board of directors of the Harvard Business School Healthcare Alumni Association, the advisory board of the Harvard Business School Student Healthcare Club and on the executive advisory board of the University of Massachusetts Lowell Nanomanufacturing Center. Mr. Green graduated from Oxford University with a Bachelor of Arts with honors in physics and holds a MBA with distinction from Harvard Business School.

SECTOR — HEALTH SERVICES

(AXD601) TWST: Would you begin by giving us a brief history of Harvard Bio, as well as an overview of what your company does?

Mr. Green: Well, brief history is tough for a company that’s 110 years old. The Harvard in Harvard Bioscience comes from Harvard Medical School, and that’s where the company began 110 years ago, but it was very small for a very long period of time. But starting in 1996, I became President of the company in a management buyout, and since then we’ve grown it from about $10 million in revenue to about $110 million last year. We make our business by making scientific instruments, and we sell them mostly to leading academic researchers at all the major universities around the world and also all the major pharmaceutical and biotech companies.

TWST: Can you explain the technology behind your InBreath tracheal scaffold and bioreactor system that’s been making the news?

Mr. Green: Sure, so let me just take you back a little bit. So the InBreath system is a clinical product. What I’d just described to you is the history of the company, which is in research products, and starting about four years ago, some clinical researchers started to adapt our life science research products for use in clinical research and then ultimately in clinical transplants, and the first product that was used in that way is what we today call InBreath tracheal transplant system. And that is a combination of a synthetic scaffold and a bioreactor, which makes an organ outside the body to transplant, and the first ever regenerated organ transplant, in fact, the first ever regenerated tracheal transplant was done in 2008, and it used that InBreath technology.

That patient is still alive five years postsurgery, where old trachea which was diseased was taken out surgically and replaced with a new one grown in the laboratory. That was five years ago, and mostly recently, just in April of this year, the first surgery of these regenerated tracheal transplants done in the United States was performed. It was performed at Children’s Hospital of Illinois and there, a synthetic scaffold plus our bioreactor was used for the first time in a U.S. patient, and that patient was actually a baby girl. She was actually 2.5 years old at the time of the surgery, and she was announced to the world about a month after the surgery, and that announcement made headlines not only across the world but also in The New York Times, and it was on the TODAY Show as well. So yes, you’re right, we’ve been making some news for ourselves just recently.

TWST: What are the most significant trends, developments or changes that you anticipate in the regenerative medicine market over the next few years?

Mr. Green: Well, I think the thing you’re really going to see is that what for many, many years has really been a promise or vision, which has been the idea of making organs acceptable for transplant, is actually going to become a medical reality, and the surgeries I just mentioned, the first one where we generated organ — and we generated trachea in this case — took place five years ago now, the first in the U.S. just a few months now. So each one of these has really pushed the technology forward and shown that it’s a better and better technology that is capable of saving patient lives.

The second surgery — there have been seven so far — was the first to use a synthetic scaffold, first to treat a patient with trachea cancer. Trachea cancer is extremely fatal; it’s more fatal than breast cancer or prostate cancer. The average survival period is only 10 months from diagnosis with tracheal cancer, and the first patient with trachea cancer was treated over two years ago now, and he was given a synthetic windpipe and he is alive and well at two years after that surgery. His condition was so bad he was only given two weeks to live prior to that surgery. That shows you how far this technology has gone from being a sort of science fiction fantasy to being a technology that can really help save patients’ lives.

TWST: Does this replace anything on the market, or is this a whole new approach?
Mr. Green: It really is a whole new approach. There really is nothing that is used to treat trachea cancer today. That’s one of the reasons it’s such a deadly disease. Patients are sometimes treated with radiation therapy, sometimes they are treated with surgery as well; but both the radiation therapy and the surgery typically fail, and that’s why you end up with these very short survival periods, only about 10 months. As I mentioned, that first patient that was treated is alive at over two years now.

"We will actually complete the spinoff of the regenerative medicine business that’s been dividended to our shareholders. If you were shareholders today in Harvard Bioscience, you’ll end up holding shares in two companies."

TWST: What is the current regimen of treatment for trachea cancer?

Mr. Green: It’s radiation therapy and sometimes, if the tumor is small, it can be surgically removed. Typically the tumors are not small, because when the tumor is small, the patients don’t have many symptoms. They might have a little cough or something, or they might have asthma type symptoms, but it’s rarely diagnosed early when it is still treatable, so unfortunately, trachea cancer often is diagnosed very late when the tumor is already big.

TWST: Can you tell us about some of the other products you’re working on?

Mr. Green: Sure. Well, that’s by far and away the most exciting stuff, and it’s really such a big opportunity and such a different opportunity to what we do in the life science research tools business that we’re actually splitting the company into two later this year. We will actually complete the spinoff of the regenerative medicine business that’s been dividended to our shareholders. If you were shareholders today in Harvard Bioscience, you’ll end up holding shares in two companies. Once the distribution is done, you’ll continue to hold shares in Harvard Bioscience, but now will be a pure-play life science research tools business, and then you’ll also own shares in the new regenerative medicines spinout company. That is by far and away the most exciting development both from a shareholder point of view and from a product development point of view.

TWST: Give us your thoughts on what kind of market is available.

Mr. Green: So I’ll answer your question twice. I’ll answer once for the life science research tools business, and I’ll come back and answer it for the regenerative medicine business. So in the life science research tools business, the markets there are pretty mature. Most of these products have been around quite a long time; it’s a very stable business. It does not have high organic growth rates. In fact, organic growth rates in that business are typically in the low single digits.

What we do is supplement that organic growth with acquisitions. We’ve made 25 acquisitions over the last 16 years, and that’s primarily what built the company from about $10 million to about $110 million in revenue. That is one side of the business. The advantage of that type of strategy in that type of business is it’s very stable. It’s really not subject to big ups and downs throughout the years, because scientists are very loyal purchasers of products. So that’s really what happens on that side of the business.

On the other side of the business, with the regenerative medicine business, there really are no options for treating these patients today. We think what we’ve got is a disruptive technology that can really change the outcomes for these patients, and then we can use the platform, and the platform really is two things. It’s using the scaffold, which are now made in a factory so we can make them in unlimited quantities, and then we combine those scaffolds with bone marrow cells taken from the patient, and because the bone marrow cells are taken from the patient there is no immune response, the body does not reject the new cells, and that’s critical because in organ transplants in general, they can take those immunosuppressive drugs or antirejection drugs for life. By using this cell therapy approach, using the cells from the patient, you don’t have that complication in organ transplant of having to take the immunosuppressive drugs.

Likewise, because you make the scaffolds at a factory, you don’t have to wait for a donor, and I’m sure you know there are waiting lists for all organ transplants today in the United States and worldwide. Although it’s early days today with trachea, we do think of this technology platform as a scaffold made in a factory, plus the cells coming from the patient can create organs for other parts of the body as well, and collaborators of ours, academic medical collaborators of ours, have already used our equipment to successfully regenerate and transplant lungs. It’s only been done in rats; it’s not been in humans yet. But all these research collaborators are working on taking that technology into human lung regeneration, and a similar work is being done by our partners. For instance, that lung program is being partnered with Massachusetts General Hospital here in Boston. We have a similar program for the development of synthetic heart valves that’s been part of the Mayo Clinic, and several top academic medical centers around the world that we have been working with on heart regeneration as well.

TWST: How strong is the intellectual property portfolio at Harvard?

Mr. Green: Again, I’ll have to divide my answer into two. So let’s look at the Harvard Bioscience life science research tools business. Intellectual property usually means patents when people use that term. Within the life science research tools business, in fact, patents are not the most important way to protect that business. The brand names and the trademarks are actually much more important. As I mentioned right at the start, we use the name Harvard Apparatus and Harvard Bioscience because we began at Harvard Medical School in 1901, and that’s an extremely strong brand name. It stands for quality and reliability in the marketplace, and that brand name has been in use for 110 years. A patent is only useful for 21 years, and that’s the legal lifetime of a patent. The useful commercial lifetime of a patent is usually much shorter than that. In the long run, building these strong brands gives you even more protection for the business than even the patent does. Well, that’s on the life science research tools side.
Now let me switch to the regenerative medicine side. On that side, the intellectual property is much more important because it’s a new business, it’s a new technology, and we have issued patents already on our bioreactor technology for a lot of other patents submitted on the scaffold technology, and we recently acquired all of the patent rights of the founder of this approach to transplantation. He is a surgeon, and his name is Dr. Paolo Macchiarini. We recently acquired all of his patent rights to both the technology and the procedure of doing regenerated organ transplants.

TWST: When you look at your technology and some of the other technology that’s out there, what role can M&A play to grow your portfolio or add to the portfolio of others?

Mr. Green: Well, M&A is very important. As I mentioned, we’ve made 25 or 26 acquisitions now in the last 16 years, and in a mature industry like the life science research tools business, you really have to make acquisitions. Otherwise you just can’t grow earnings per share particularly fast if the organic growth rate of the industry is only 3% or 4%. Every company in the industry, including ourselves, makes acquisitions to supplement product lines, expand distribution channels overseas and add technology to the distribution channel you’ve already got. We’re obviously no exception to that. We’ve made lots of acquisitions, and that’s a big part of our growth in the past and will continue to be a big part of our growth in the future. On the regenerative medicine side, there’s really not much for all four acquisitions of businesses. I think we’re really a pure-play regenerative medicine company there, and you may see us acquire patents and intellectual property, but I don’t think you’re going to see us acquiring businesses.

TWST: Chane Graziano, your former CEO, retired recently, and you became the new CEO. Looking at the current management team and your current operations, are there any more changes on the horizon?

Mr. Green: Yes, we do intend to bring in a new CEO, and in fact, we’ve hired a search consulting firm to help us with that, because when the spinoff takes place probably roughly around September this year, I’ll become the CEO of the new spinoff company. I’ll remain as a Director of the life science research tools business. I’ll also remain as a major shareholder, but I’ll no longer be present at that company. So we’re currently looking for a new CEO who will focus exclusively on the life science research tools business.

TWST: You’ve been with the company since March of 1996. What caused you to join this company? What were the challenges, opportunities that you saw? As a personal report card, have you met the goals that you set for yourself?

Mr. Green: Well, it’s a very interesting question. Let me just start by saying, I basically married into it. My wife was working as a Product Manager for Harvard Apparatus back then. She was working on developing a clinical product, which in the end unfortunately went bankrupt, but she was working for the company. The company was in financial trouble. I had just finished a stint of work with my former employer and wrote a business plan for her to try to finance the business, and somewhat to my surprise, the venture capitalists who I presented the plan to said, “David, this is a great plan, we’d like you to run it” — and they basically offered me a deal I couldn’t refuse. I didn’t refuse it, and I was only about 30 or so at the time, so they said get some gray hair, so I found Chane Graziano, the man who recently retired, and we went back to the VCs together, said, “OK, here’s the team, are you willing to back me and Chane to run this business?”

They said yes, and that was 1996, and the goals we set ourselves back then were distinctly more short-term. We certainly did not have a 16-year business plan. I don’t think Excel had enough columns in it to enable you to do a 16-year business plan back then, and instead we focused more on the short term. Those sort of four to five years and the plan really was actually very similar to what we’ve executed. It was a combination of organic growth plus acquisitions to build the company over the long term. In many ways we have met the goals of that original plan. We went public in 2000, and that was probably earlier than we anticipated. The one part of the business we could never have anticipated back then was the emergence of the regenerative medicine business.

TWST: Obviously, the HART spinoff is very important, but summarize some of the other strategic priorities for the remaining of 2013 and through 2014.

Mr. Green: Well, for 2013 I don’t have any other strategic priorities. That’s more than enough for us to get through, that the spinoff of the business is a very significant value-creation opportunity for your shareholders. Today we report our consolidated earnings per share, which includes the investment in the regenerative medicine business. Once that is spun off and separately capitalized, you’ll see the full earnings per share of the core life science research tools business.

In addition, you’ll have the share ownership stake in the regenerative medicine business, which will be dividend to the shareholders, so its harder to put a valuation on that business, but it’s worth something, and the shareholder is going to own that business separately from owning Harvard Bioscience’s pure-play life science research tools business. So that is by far the top priority, plus managing the transition with a new CEO coming in, I would say, is more than enough strategic-level work for this year.

Once that is over though — let’s move to 2014 as you suggested, and again let me answer your question twice. So the strategic priorities for the life science research tools business will be very much increasing the organic growth rate and getting back to doing acquisitions. We’ve not done many acquisitions in the last couple of years, because our cash flow has been down because of the investments in the regenerative medicine business. Once the spinoff is done, the cash flow will back up and we have the borrowing base again and the cash flow to make the acquisitions again, so I think you’re going to see us return to doing a higher rate of acquisitions starting in 2014. So that really is the strategic priority on the research side.

“Every company in the industry, including ourselves, makes acquisitions to supplement product lines, expand distribution channels overseas and add technology to the distribution channel you’ve already got.”
On the clinical side, the strategic priority is going to be getting through FDA clinical trials, to get to FDA approval so we could market the products broadly to the patient population that needs them.

**TWST: Do you have the balance sheet to support it all?**

**Mr. Green:** Yes, we do. So the Harvard Bioscience today comes in about $20 million in cash, and we have about $20 million in debt at the same time, so you have zero net debt today. So we’re essentially unleveraged. Some of that cash is going to be put onto the balance sheet for us to capitalize it prior to the spinout at that point. Harvard Bioscience will have about $25 million or $30 million of debt, but it will now have an income statement that will not have expenses of the regenerative medicine business on it, so it’ll actually still be a very low-leverage business.

**TWST: Do you think the market understands your approach and what you’re trying to do?**

**Mr. Green:** I think there are a large number of investors who do understand it, because we did an IPO road show for the HART business, that’s the regenerative medicine business, in about April of this year. We met with well over 100 fund managers there. Prior to that, because of the JPMorgan Conference in January, we’d also met with something similar, like 100 fund managers. Because of that intense outreach we were able to inform those new investors — who drove up the Harvard Bioscience stock price to well over $6 at one point — of new investors and on current investors as exactly what was going on both the base business and with the spinout. So yes, I do think people pretty much understand what we’re doing.

**TWST: In conclusion, if you were sitting down with a group of potential long-term investors, what two or three reasons would you give them to take a look at Harvard Bio today?**

**Mr. Green:** I would say today we’re in a position where you can buy one security, Harvard Bioscience, HBIO, in the marketplace today, and about September you’ll own two securities; you’ll own one in a pure-play life science research tools business and you’ll own one in a pure-play regenerative medicine business. The life science research tools business is a low-volatility, steady-eddy kind of business. It doesn’t grow particularly fast, but it’s a very nice cash flow business. That’s what you’ll own in the Harvard Bioscience stock.

And then you get these shares in the regenerative medicine business, which is an investment-stage business. It’s going to be burning cash for at least the next two to three years — but assuming this works, and we do have certain patients who can treat it. So I think there is a very good chance of this working, and this is going to be a hundreds of millions of dollars a year of revenue opportunity for us, which in the medical device space would typically lead to a billions-of-dollars market cap. So that’s what I think is the most important thing for investors to focus on today, is that surely the company is going to be two companies, not one company, and you can have this upside in the regenerative medicine business, but you can have the security and the predictability of the life science research tools business.

**TWST: Excellent. Anything you’d like to say, anything we’ve overlooked?**

**Mr. Green:** No, I think that was a great list of questions.

**TWST: Thank you.**

**DAVID GREEN**  
President & CEO  
84 October Hill Rd.  
Holliston, MA 01746  
(508) 893-8999  
(800) 272-2775 — TOLL FREE  
(508) 429-5732 — FAX  
www.harvardbioscience.com  
e-mail: info@harvardbioscience.com
COMPANY INTERVIEW

CAS Medical Systems, Inc. (CASM)

SECTOR — HEALTH SERVICES

(TXD606) TWST: What is CASMED?

Mr. Patton: CAS Medical Systems, ticker CASM, is a microcap medical products company in Branford, Connecticut, that’s been around since the 1980s developing high-quality patient monitoring equipment. We sell a number of different products, but chief among them is a fascinating technology that measures the oxygenation of the tissue of the brain during surgery or other episodes of patient critical care. That product is our FORE-SIGHT brand of cerebral oximeters, and it can detect dangerously low levels of oxygen in the brain that would otherwise go undetected without this direct method of monitoring.

In addition to FORE-SIGHT, we sell a series of vital signs monitors under the brand 740 SELECT, for lower acuity patient care, and we have a noninvasive blood pressure technology that we sell to other manufacturers who then incorporate that technology into their own monitors. New versions of all three products, with state-of-the-art features and design, are being introduced this quarter.

TWST: Speaking about your FORE-SIGHT ELITE Oximeter and the 740 SELECT; can you tell us about the market size for these products and the possible penetration?

Mr. Patton: We think the current market size for cerebral oximetry worldwide is approximately $80 million, but that only represents about 35% penetration of the primary cardiac heart surgeries and low levels of penetration for many other applications and procedures. Considering all its applications, we think the total addressable market for cerebral oximetry is $400 million or more. With FORE-SIGHT, including our new FORE-SIGHT ELITE monitor that will be introduced this quarter, we believe CASMED is uniquely positioned to both gain market share from competitors and drive further market penetration.

The market segment for vital signs monitors is approximately $250 million. Our new 740 SELECT, which also should be released this quarter, replaces a very successful 10-year-old product line that has seen worldwide sales of over 20,000 monitors. Building on that brand value, we believe the 740 SELECT will enable us to increase our share of that market as well.

TWST: From a scientific point of view, how does the Cerebral Oximeter product work?

Mr. Patton: It’s a fascinating technology in which you place a noninvasive sensor on the forehead that emits an infrared light that goes through the skull and into brain tissue. The infrared signal is partially absorbed by the substance we are interrogating — oxygenated and deoxygenated hemoglobin — and partially refracted back to photo detectors. Applying a complex algorithm to those signals, we can determine the absolute oxygenation levels of the cerebral tissue. And the clinical support for our product is robust, with more than 200 published papers, abstracts and scientific posters published since 2005 on the utilization of FORE-SIGHT. These publications also show the importance of monitoring brain oxygen; a drop in brain oxygenation can result in serious complications including stroke or even death.

TWST: You have a business relationship with Covidien, one of the leaders in the medical device industry. How did that develop?

Mr. Patton: Our partnerships with Covidien and another industry leader, Masimo, relate to our Vital Signs Monitor. Those companies both provide us with their high-quality pulse oximetry component technology, which we incorporate into our 740 Vital Signs Monitor to provide a best-in-class product for our customers.

TWST: How strong is CASMED’s intellectual property portfolio?

Mr. Patton: We pride ourselves as being a company that continually innovates, and we think we have a solid intellectual property estate to protect much of that innovation. In particular, one of our clinical advantages with FORE-SIGHT is the very high degree of accuracy that we have with our monitor compared to our competitors. We believe our patents protect some of the most effective methods to obtain that level of accuracy.

TWST: What are your priorities for the next 12 months to 18 months? What would make that time frame a success?

Mr. Patton: CASMED is at an exciting inflection point. When I joined the company three years ago we raised capital from Thomas, McNerney & Partners, a venture capital group that
specializes in medical technology. With that capital we completely remade the marketing organization and our sales organization, and launched the development efforts to further enhance our product portfolio with three new product platforms. All of that now is culminating in the launch of those three new products, one in each of our three major product areas, in the third quarter of 2013.

“"All these devices we sell go through the 510(k) approval process, and our most recent experience with the FDA has been terrific. Our new FORE-SIGHT ELITE monitor received approval 87 days after we filed our application.”

What would make this a terrific success is to execute a flawless launch of these products successfully into the market, to drive revenue growth and improve our margins, gain operating leverage in our financial results and drive the company towards profitability. Specifically, I should note that the new FORE-SIGHT ELITE Cerebral Oximeter has a much lower production cost than its predecessor, which we believe will lead to significantly improved margins going forward.

TWST: Is there anyone else doing anything similar, or do you have this market to yourself?

Mr. Patton: The cerebral oximetry market was established by a company called Somanetics, which was subsequently purchased by Covidien. Somanetics had the market to itself for many years until we introduced our technology. We are differentiated on many technical aspects, but as I mentioned earlier, one of the distinguishing features that our clinicians report is the level of accuracy of our monitor, which gives them the confidence to either intervene or not intervene during surgery based on the readings our monitor provides.

TWST: When you look at your technology and some of the other technologies out there, what role can M&A play to grow your portfolio or perhaps add to the portfolio of others?

Mr. Patton: The principal call points that we have are the anesthesiologist, the perfusionist and, to a lesser extent, cardiac surgeons. I think giving our sales force products that go into that same call pattern, through development or acquisition, could leverage the distribution we now have and allow us to gain synergies from that. On the other hand, there are many important players in the patient monitoring sector that would benefit from a competitive standpoint to have the FORE-SIGHT technology in their product portfolio for the same reasons.

TWST: What’s the funding and financing status of the company at this point? Are there items on the agenda to approach either?

Mr. Patton: Yes. Last week we announced completion of a fund raise of $6.5 million through the sale of common stock, which in addition to the cash we had on hand should be sufficient to get us to cash-flow breakeven and on to profitability.

TWST: Introduce us to the top-level management team. Has it undergone any changes, and are you looking to make any additions?

Mr. Patton: We have a fantastic group of senior managers, most of whom joined the company in the last three years with many, many years of experience in medical products development, distribution and marketing. Matt Herwig is our Senior Vice President of Sales and Marketing and is a real professional. He had a terrific 19-year career through the Mallinckrodt, Tyco, and Covidien. John Gamelin is a rock star in medical technology, and he was recently promoted to head up our R&D organization. Paul Benni is a brilliant scientist who developed the FORE-SIGHT technology and is responsible for the continued improvements in the algorithms we use. Jeff Baird, our CFO, is a rock-solid guy who’s indispensable in this organization. So we have the major management positions filled with terrific people, and we’re not looking to expand at this point.

TWST: Would you comment on the FDA approval process for devices such as yours?

Mr. Patton: All these devices we sell go through the 510(k) approval process, and our most recent experience with the FDA has been terrific. Our new FORE-SIGHT ELITE monitor received approval 87 days after we filed our application. Both our MAX IQ noninvasive blood pressure and our 740 Select monitor received FDA approval in 92 days following the application filing. The average time to gain FDA clearance is significantly higher than this, so we are pleased with the recent experience. I think we understand the regulatory process very well and have a terrific relationship with the FDA.

TWST: Do you have any other collaborations or partnerships with the big medical device companies?

Mr. Patton: Not at this time. I do think that the future of cerebral oximetry is the incorporation of the technology as a module into other more comprehensive monitoring devices, so we have had ongoing discussions with at least a couple of industry leaders regarding how that development might proceed.

TWST: What does the shareholder base consist of as far as retail and institutional shareholders? Do you see any changes in those positions?

Mr. Patton: The company went public in the mid-1980s, and since then we’ve had a relatively large retail component owning approximately 13 million shares. In the fund raising completed this July we sold 5.2 million shares, mostly to a handful of high-quality institutions, including Deerfield, that we hope will be long-term holders. As we grow, I anticipate we can attract greater institutional ownership over the coming months and years.

TWST: In your discussions with the investment community, are there any recurring questions or misperceptions that you encounter? Do they understand your products, your strategies and your abilities?

Mr. Patton: I think that we have been way under the radar for most investors. We’re a small-cap company that, I would say, has been moving sideways for many years. But now I think the story of a sleepy niche company is behind us. We are introducing a strong new product lineup, and have the management team and an improved distribution network primed to make the introductions a
success. We’re excited about the future and our ability to drive the revenue growth and return the company to profitability.

**TWST: What are the key metrics or key events that investors should focus on as they track CASMEd’s performance?**

**Mr. Patton:** I think the near-term milestones would be the formal introduction of our 740 SELECT and of our FORESIGHT ELITE monitors; the commencement of a multisite interventional outcome study we expect will begin in Q4 of this year, and a return to revenue growth.

**TWST: What kind of corporate culture are you trying to develop at CASMEd?**

**Mr. Patton:** I’d say the culture has been remade over the last couple years. I’m excited about how our associates, our managers and the whole team is working together with a high level of communication and respect. We are committed to integrity, setting a standard of excellence, being passionate about improving patient care, and being accountable to our partners and customers. These are all things that we preach every single day, and I think that the way our new products were developed are a testament to that commitment.

**TWST: What are the key summary points today that compel investors to include CASMEd as part of their current portfolio and as part of their longer-term investment strategies?**

**Mr. Patton:** I think CASMEd is at a real inflection point as we continue to put the final pieces of the turnaround into place. With this most recent fund raise there is no longer an overhang on the stock where people are wondering about our ability to get to profitability with the cash on hand. We have a remade culture, we have a terrific and newly established management team, and we have new products in each of our major product categories that we think will catapult the business forward in the short term.

In the long term we see the potential for our technology to both take market share from our competitors and to expand the market for cerebral oximetry. I believe we’re at the early stage of watching cerebral oximetry become a standard of care, and that CASMEd is uniquely positioned in the marketplace to take advantage of that. There’s a lot of runway in this marketplace; we think it will be a fast growing marketplace, and CASMEd would be an interesting to watch for both the short and the long term.

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

**Mr. Patton:** No, I think it’s been terrific. I appreciate the opportunity to reach some of our current and potential investors.

**TWST: Thank you. (KL)**

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**THOMAS M. PATTON**  
President & CEO  
CAS Medical Systems, Inc.  
44 East Industrial Rd.  
Branford, CT 06405  
(203) 488-6056  
(800) 227-4414 — TOLL FREE  
(203) 488-9438 — FAX  
www.casmed.com
COMPANY INTERVIEW

PhotoMedex, Inc. (PHMD)

DOLEV RAFAELI was appointed Chief Executive Officer of PhotoMedex, Inc., in 2011. Dr. Rafaeli joined Radiance in February 2006 as President and CEO. He has over 22 years of experience managing international operations. Prior to joining Radiance, Dr. Rafaeli served from 2004 to 2006 as President and CEO of the USR Group, a consumer electronics products manufacturer, managing operations in Israel, China, Hong Kong and the U.S. Between 2000 and 2004, Dr. Rafaeli founded and served as General Manager of Orbotech Ltd., an automated optical inspection capital equipment manufacturer for the electronics industry in China and Hong Kong. Between 1997 and 2000 Dr. Rafaeli served as CEO of USR Ltd, a global electronics contract manufacturing company. Previously, Dr. Rafaeli served as the director of operations and the manager of the Arad manufacturing facility for Motorola in its Land Mobile Product Solutions division, manufacturing and distributing communications, consumer and other infrastructure electronics products in excess of $400 million annually. Dr. Rafaeli graduated with B.S. in industrial engineering and management cum laude from the Technion, Israel; an M.S. in operations management from the Technion, Israel; and holds a Ph.D. in business management from Century University.

DENNIS M. MCGRATH, upon completion of the merger with Radiance, reassumed his role of Chief Financial Officer, in addition to his roles as President and Director of PhotoMedex, Inc., to which he was appointed in July 2009. Mr. McGrath had served as its Chief Financial Officer and Vice President of Finance and Administration from January 2000 through November 2009. Mr. McGrath has held several senior level positions in prior endeavors, including, from February 1999 to January 2000, serving as the Chief Operating Officer of Internet Practice, the largest division for Awerthink Consulting Group, Inc., a public company specializing in business consulting and technology integration. Concurrently, from August 1999 until January 2000, Mr. McGrath served as Chief Financial Officer of Think New Ideas, Inc., a public company specializing in interactive marketing services and business solutions. In addition to the financial reporting responsibilities, Mr. McGrath was responsible for the merger integration of Think New Ideas, Inc. and Awerthink Consulting Group, Inc. From September 1996 to February 1999, Mr. McGrath was the Chief Financial Officer and Executive Vice President of Operations of TriSpan, Inc., an internet commerce solutions and technology consulting company, which was acquired by Awerthink Consulting Group, Inc., in 1999. Mr. McGrath graduated with a B.S. in accounting from LaSalle University in 1979.

SECTOR — HEALTH SERVICES

(AXD608) TWST: Would you begin with a brief overview of PhotoMedex and an overview of your operations?

Mr. McGrath: PhotoMedex is a global skin health company; we provide aesthetic and disease management solutions to dermatologists, professional aestheticians and consumers. Our products are services that address psoriasis, vitiligo, acne, photodamage and actinic keratosis, which can be a precursor to skin cancer. In 2011, PhotoMedex completed a reverse merger with Radiance, Inc., and added a range of at-home devices under the no!no! brand for hair removal, skin rejuvenation and acne. We also offer a professional product line for physician clinics and spas that address acne, skin tightening, psoriasis and hair removal.

TWST: The company and the business is divided into two distinct segments, disease management and aesthetics. Could you give us a sense of the contribution you get from these segments?

Mr. McGrath: We go to market in three business segments. The consumer segment, which currently is our largest segment, is about 80% of our business. We also have a segment we call physician recurring. It’s a channel through which we sell skin disease therapies, particularly for psoriasis and vitiligo, as well as skin-rejuvenation products targeting the physician market, and it
Dr. Rafaeli: If I may add here, most of what we do is not about what products we sell, but how we sell them. We have a very wide technology base, we have close to 200 patents, we have a lot of devices, we have over 90 FDA clearances, and that’s the technology story. But what drives revenues is our go-to-market approach. We drive patients on the health care services side. We drive sales on the consumer side, because we invest heavily in the advertisement. We don’t sit back as a technology company and hope for somebody else to get the word out; we control the message, timing and which markets to target, and by doing that we control sales in those markets, we control the growth in those markets, we decide which segments in the markets we go into and when.

Once we identify a profitable segment we scale it up; we increase targeted advertising to that segment. When we control the message, our partners benefit from this expertise as we drive the business flow to their door, whether it’s a patient coming to a doctor or a consumer coming to the retailer. This is how we ensure that the growth happens. We look at it as a platform driven by two distinct disciplines: advertisement and customer service.

TWST: Could you give us a sampling of some of your proprietary products, where they are found and some of their applications?

Mr. McGrath: As Dolev said, the companies have combined to create what we consider a full product life cycle, from the genesis of an idea through the development stage, attracting the right scientific advisory board, monitoring these products in the physician community and ultimately miniaturizing them and selling directly to the consumer. We have leveraged the natural life cycle of these products by developing a world-class marketing platform that has simply cracked the code to draw consumers in, so you find our diversified product offerings along that entire spectrum.

In the physician community, our XTRAC brand name is the safest and most effective therapy for psoriasis. It’s a laser device that emits UV light at specific wavelengths that clears psoriasis from the patient’s body for extended periods of time. This fulfills a previously unmet need in the psoriasis patient’s life, and it works very painlessly. We also go to market with a very unique business model for the physician and one that creates recurring revenue.

In addition, we sell skin care products to physicians who in turn retail them to their patients. These products have two proprietary ingredients: DNA repair enzymes, which reverse the effect of sun damage, and copper peptides. Copper has been studied for years for its wound-healing applications, and it’s proven to increase the collagen and elasticity of the skin. Historically these products have been sold into the physician market. We’ve adapted that model to now include a consumer platform, selling directly to the consumer.

A perfect example of a product offering evolving along that life cycle continuum is a noono hair brand. Long-lasting hair removal was at one time only offered in the physician’s office using large and expensive laser devices. Now a consumer can enjoy this benefit in the privacy of their home at a substantial cost savings. We market our noono hair-removal system as well as other medical devices made for consumers, meaning they are safe, effective and generally no larger than the palm of your hand, and now are sold in more than 50 countries.

Dr. Rafaeli: Let me add on to this. You asked about the XTRAC business. When we merged, we actually looked at the XTRAC as the business that had the highest upside in the merger of the companies, and focused on how best to market this brand. Historically, PhotoMedex was placing the XTRAC devices with doctors assuming that the doctor could either advertise or bring his current patients into the therapy. We changed that strategy after the merger.

Just to understand how this business works, think of it as a vending machine that we place with a doctor. Our cost of placing that vending machine is a fixed expense of about $25,000. Historically, PhotoMedex would place it with a doctor hoping that the doctor would bring the patients. We look at it as more like a chain of coffee shops where the value of the business comes from how many shops you have, how many cups of coffee are being served in each shop and the price of the cup of coffee. We've dealt with improving the results in all three components.

Since the merger, we went from 278 franchisees, or vending machines, to over 450. Over the last year we significantly increased the volume of treatments delivered in each location, and we also increased the price that we collect by approximately 20%. The end result is that the physician is making a lot more money, and so is the company. Each additional treatment delivered to a patient contributes more than a 90% margin, so it is not only important for us to increase the number of vending machines or franchises, but also it is important for our national advertising to drive additional patients to the door of the physicians.

Frequently in the last month, we’ve been asked about ObamaCare and the impact of ObamaCare on what we do. Very interestingly, we actually think ObamaCare has a positive influence on this part of our business. ObamaCare is all about getting the most efficacious and most affordable treatment to patients. Historically, PhotoMedex was dealing with the physician, so it was a business-to-business sale. We now bypass that. We made this a business-to-consumer sale. We advertised to consumers the existence of this most efficacious treatment. Since we’re very good at advertising, we get the patients to the doctors, the doctors make money, we make money, the patients get the most effective treatment, and the insurance companies end up paying much less than they paid before. So in a way this whole triangle of physicians, patients and insurance company gains, and we gain in the process.

TWST: Let’s talk a moment about the Neova product. What’s the competitive landscape for you in that aesthetics market, and what do you think is PhotoMedex’s edge over the other players?

Dr. Rafaeli: We started selling consumer products when...
allowing us to be more in the midrange of pricing rather than being in the U.S. and Japan just in Brazil, the U.K. and Germany, there’s 140 million in population. So if we get to the penetration that we have launched Germany, and between the U.K. and Germany there’s and 2012 our sales in the U.K. went up sixfold, and earlier this year so if we only penetrate 1% of that market, that’s 2 million more units. entering the Brazilian market, with 200 million people in population, or 1% penetration. We’ve recently announced that we are together it’s about 450 million people, so we serve about 1% of the population, or 1% penetration. 

Mr. McGrath:

TWST: When you look at your products and your services and some of the other products and services that are out there, what role will mergers and acquisitions continue to play to further grow your own portfolio, or perhaps add to the portfolio of others?

Mr. McGrath: The management and the board of the
company think about the future in terms of how do we build a company that has $1 billion or more of sustainable recurring revenue. That seems like a bold idea, given that we’re a $250 million company today. But the roots of that future success are already in what we are doing and executing against. So as we think about the growth, the platform — and basis for that answer is built upon what are we doing and how are we growing the business and identifying the key drivers.

In the consumer area, Dolev has already mentioned we’re growing geographically. We are optimizing the distribution points inside the areas in which we are already operating. Bed Bath & Beyond in the U.S. is an example of that, as are the Spanish language commercials in the U.S. we recently launched. We also have a robust pipeline of products that we believe can be successfully launched on this sophisticated marketing platform, as well as leveraging those skill sets into the physician area. An example of that is the ongoing direct-to-patient advertising that is making patients aware that the best therapy for their disease can be found at their local dermatologist, and we’re supplying that answer for those patients.

As we think about all of those aspects of the business, there are ways that M&A may be able to accelerate the achievement of that target, so the mindset of board and management is that we will be opportunistic. Certainly our mindset is that we will not do anything that will be dilutive to our earnings. The board and management are significant owners of the company and consequently are perfectly aligned with its broader shareholder base, and therefore we are very sensitive to growing the top line in parallel with generating significant profits.

In the ownership in the company. I emphasize that because this did actually trading volume going on, and there’s institutional participation that are currently trading at $16 per share. But not only that, there’s obviously, not only have they made good decisions for themselves, but the decision was good for their shareholders as well, because whoever was a shareholder at the time had shares at $5.50 per share. And the shareholders of PhotoMedex, when they approved the merger PhotoMedex was trading at $5.50 per share. The board and the management agreed to change their golden parachutes into equity in the company and the other members of the PhotoMedex management team of PhotoMedex stays on board. The nice thing about this merger is that when we made the decision to merge the two companies, the precondition of the merger was that the existing management is perfectly aligned with its broader shareholder base, and therefore we are very sensitive to growing the top line in parallel with generating significant profits. So profit impact is a key factor in deciding how and what we do with the tool of M&A.

There’s been a lot of recent activity in our space over the last six to eight months. Many companies have combined at robust multiples of their sales platform. That is both good and a challenge. It’s good because the value of the selling entities has been significant. The challenges are the higher the purchases, the more difficult it is to avoid being dilutive on your current operations. But we continue to explore strategies that can accelerate achievement of our goals, and we’re open-minded to how M&A could factor into that.

TWST: How strong is the intellectual property portfolio as far as patent protections? How much effort is going in to add to that portfolio?

Mr. McGrath: We are blessed to have a very unique position in that area. Companies of our size typically don’t have as robust a portfolio as we do. We have more than 200 patents, both pending and filed, as well as trademarks, and we’re very proud of what that represents in terms of protecting our past and our future. In addition, we have more than 90 FDA 510(K)s; another feather in the cap of our technology people in terms of building great technology that has this unique position and can get clearance from the FDA to market them.

TWST: Can you tell us what are the greatest opportunities from PhotoMedex over the next several years? Is there a chain of events that could lead this company to substantially exceed expectations?

Mr. McGrath: I think that interwoven in the answers to your questions so far is the road map for that accelerated success. It’s growing the consumer platform on multiple axis, both geographic expansion as well as launching new products and optimizing the distribution points inside that. In addition, leveraging that skill set into the physician community to create awareness among patients that the best therapies for their disease can be found in the hands of our participating physicians, as well as broadening the distribution of our skin care products across multiple segments, both the consumer and the physician area. We think that M&A could potentially play a role in exceeding those expectations, again being opportunistic for what those opportunities represent.

TWST: Give us your comments on the experience and leadership credentials of your top-level management team.

Mr. McGrath: Another way of saying that is yes, we are old, we have lot of experience, we feel it’s very synergistic. The depth goes well beyond Dolev and me. As you look into the next level of leadership, we have a very senior, seasoned leadership team that has expertise across all the key dimensions that you need for not only sustaining the success we’ve enjoyed so far, but achieving the robust, bold plans that we have in place. That talent is worldwide; whether in Europe or in Israel or in South America, we think we have a very deep talented team. You pick the specific category — regulatory, intellectual property, manufacturing, operations, marketing, sales force — we think we have recruited some of the best to be able to build to that target.

Dr. Rafaeli: Let me add on to this. When we came to the merger, the precondition of the merger was that the existing management team of PhotoMedex stays on board. The nice thing about this merger is that when we made the decision to merge the two companies, PhotoMedex was trading at $5.50 per share. The board and the shareholders of PhotoMedex, when they approved the merger agreement, agreed to change their golden parachutes into equity in the company. So they believed in not only the company, which they have worked in — I believe at that time Dennis had more than 10 years in the company and the other members of the PhotoMedex management had been in the company for an even longer period of time. They believed that converting their cash golden parachutes into equity in a company that was trading at $5.50 per share was a good decision.

We are now close to two years after the merger, or two-and-a-half years after we decided to merge. Our stock is trading at $16. So obviously, not only have they made good decisions for themselves, but the decision was good for their shareholders as well, because whoever was a shareholder at the time had shares at $5.50 per share that are currently trading at $16 per share. But not only that, there’s actually trading volume going on, and there’s institutional participation in the ownership in the company. I emphasize that because this did not only happen on the public company side, the PhotoMedex side,
but it also happened on the Radiancy side. All of the management members of the Radiancy side had equity position in the company; they all are shareholders in the company, and they all saw that go from $5.50 per share valuation to $16.

Now I mention that because your previous question was about M&A. I think the biggest hurdle that we find when we come to look at M&A opportunities is, again, not about what they have in terms of technology, nor even how they go to market, because we know we have a very good solid platform to take things to market, but it usually is evolving around the HR factor, where we need to deal with entrenched management teams that are either afraid of making changes or afraid of losing what they have today. We are looking for a team that is invested in making the company successful. We don’t think in terms of taking a company from X to 2X.

In the case of PhotoMedex, PhotoMedex was a $32 million-a-year company and grew to $220 million in 2012. So we managed to grow the company within two years by sevenfold, which is nice. If we merge with a company that is equal in size, let’s say $200 million, $250 million in size or $300 million in size, we’re not looking to cut away the management and save by that. We’re actually looking to make sure that the talent stays, that the knowledge of the market, the knowledge of the distribution, the knowledge of the R&D, the knowledge of the operations, the knowledge of the company’s finances stays. What we want them to do is to take a leap of faith in their own company and choose not to opt for the golden parachute, but rather to stay in and take an equity position, like we all have.

**TWST:** Does Wall Street give you recognition for where you have come from and where you’re going?

**Mr. McGrath:** Yes and no. We’re a year and a half postmerger, so to some degree we are still considered as an early entrant to the Wall Street game, even though PhotoMedex has been a public company for a long period of time. During that year and a half we have eight analysts that have covered the company, so there has been some exposure. We have an active investor relations program. I think that the growth has been so significant and the profitability has been so robust that there are some doubters that this can continue for the indefinite future.

Obviously, as we’ve discussed, the management and the board clearly understand that they have a significant bet on the line. Because we own 35% or more of the company, we are focused on the long term, not this week or next week or even this quarter; it’s how we build a large sustainable world-class business. So there are doubters, and therefore there are those who are betting against us, which I think holds down the stock price to some degree. But each of the analysts out there have a higher target number than where we’re currently trading at, and we are striving to prove them right.

**TWST:** How could the investment community better understand PhotoMedex? As you speak with potential investors, customers, analysts in the industry, what are the misperceptions, in your opinion, that they have that you need to confront?

**Mr. McGrath:** We are continuing to build multiple legs to our platform here. The consumer area clearly has been a very credible success. We believe that expanding the product line in that area will help build greater confidence in the investment community.

The physician recurring business segment, particularly our XTRAC psoriasis unit, is growing by significant year-over-year and quarter-over-quarter amounts, and yet still represents a smaller portion of our revenue. As that becomes a larger business, I believe it will alleviate some of the investment concern about relying upon one segment more than the other.

Inside that physician recurring segment there are multiple legs to that stool, including our Neova skin care products as well as other product offerings in this group. As those offerings continue to show growth, I believe the doubters will be ultimately be forced to back off, giving the stock the opportunity to reach for higher levels at an accelerated pace.

**TWST:** Summarizing your strategic priorities for the remainder of 2013 through 2014, what’s top of the list?

**Mr. McGrath:** Continue to execute our plan for our geographic expansion on the consumer front. Germany has just begun, and we think it presents a very robust market for us to penetrate and with which to optimize the marketing programs. We are very optimistic about launching in Brazil, where we’ve recently acquired a company from which to give us a base to launch our programs. The demographics there seem to be right for great success.

We are also looking at launching in other areas and launching other products in that consumer platform. A great deal of our attention is being directed at the XTRAC business, particularly here in the U.S. There is a big patient population that is currently underserved and their needs are unmet. We know that we have a solution to meet that need, and we believe that creating patient awareness could drive that business, which is approximately a $20 million business today, to grow to 10 times that. We think that we have figured out the roadmap to that success and are busy executing it. I think over the next six to eight quarters, investors will be delighted to see a substantial amount of success in that segment of our business.

**TWST:** Summary statement for a potential investor:

**Why buy this stock today?**

**Mr. McGrath:** The company has a history of success, a winning formula for future success, and the current stock price is at a very, very attractive valuation, trading at about six times last year’s adjusted income. We think that there is significant value there given the technology, the marketing platform and the growth prospects of our company.

**TWST:** Thank you. (KL)
which is growing roughly 4% to 6% depending upon the market, so revenue growth over 30%. This compares to the AAA market, probably have around 5% market share there but that's growing marketing organization in Europe and are still in that process. We market. We've only just recently started to build a direct sales and zero when the device was introduced. Outside the U.S., it varies by market share in 12% to 14% range, and of course that's growth from that in terms of market share, we right now estimate our U.S. platform over time, while we develop other new devices.

When you look at our revenue this year, which we guided to be $128 to $134 million, that really largely comes from AFX, and we currently sell, which is called AFX, and it is our primary product. This includes the device we have filed multiple PMA supplements and introduced several different enhancements, updates and upgrades to the original product over the last few years. This includes the device we currently sell, which is called AFX, and it is our primary product. When you look at our revenue this year, which we guided to be $128 to $134 million, that really largely comes from AFX, and we would expect to continue to enhance, improve and upgrade that platform over time, while we develop other new devices.

In terms of the demand for AFX, if you want to measure that in terms of market share, we right now estimate our U.S. market share in 12% to 14% range, and of course that’s growth from zero when the device was introduced. Outside the U.S., it varies by market. We’ve only just recently started to build a direct sales and marketing organization in Europe and are still in that process. We probably have around 5% market share there but that’s growing very rapidly. We announced our Q2 results just recently, with revenue growth over 30%. This compares to the AAA market, which is growing roughly 4% to 6% depending upon the market, so you can see that our growth is largely market share capture.

TWST: Your Q2 earnings growth was a fabulous 33%, after an equally stellar Q1. Can you share with us why you’ve raised revenue guidance for remainder of the year?

Mr. McDermott: The main reasons are good momentum with the current products driven by our seasoned sales force. This is a very clinically intense device, as are all the other devices in this space, so the capabilities of the sales force and their relationships are very important. We have a very good team that has been in place for quite a while now; they are getting traction, the product is performing well, the doctors are comfortable with it.

We have also rolled out a new initiative, which we call PEVAR, and that is a percutaneous indication for AFX. We did a clinical trial a couple of years ago to demonstrate the safety and effectiveness of doing these procedures without a surgical incision, so instead going over a guidewire. That technique has gained quite a lot of interest and enthusiasm, both from the perspective of the patients as well as the clinicians offering this option to their patients. So we are in the early stages of introducing PEVAR.

We received our approval to broaden our indication for AFX to include PEVAR in April, ran our first physician training courses in May, and now we’ll be running courses over the remainder of this year and into next year. In these courses we bring physicians in and we train them on this technique, and what’s unique is we have trained our sales force to conduct the training and certify physicians in PEVAR. The closure device that closes this little hole for the delivery system is actually an Abbott product, and we collaborated with Abbott on this clinical trial, but as it relates to the training and the clinical support in the cases, our sales force has now been trained and certified on this technique, and it’s really the only EVAR sales force with that capability. This gives us a bit of a unique position in the market, being able to provide clinical support for physicians who want to do percutaneous EVAR.

TWST: When you look at margins for this company, what do see as the key factors, or the critical variables that
influence margins over the next two or three years?

Mr. McDermott: In terms of gross margins, the primary variables will be price and product mix. Price will change; we expect there to be more price pressure for all devices in the years ahead. But those prices also depend upon the markets, and different markets have different prices as you know. As our business grows in Europe, our average selling price globally will come down, which will affect our margins. We do expect to get some operating leverage from higher volumes to offset that, and we will continue to work on price. As we go into more and more markets, we’ll also experience different product mix margins as well as geographic margins, but all that rolled together, we forecasted our margins to be in mid-70s over the next several years.

TWST: Endologix has a very impressive patent portfolio with 17 U.S. patents, 361 allowed claims. Can you speak to the strength of the I.P. portfolio? How that’s going?

Mr. McDermott: It’s going really well. When we acquired the Nellix Technology a couple of years ago, we added a good number of patents with that transaction. Within the last year we added a license to polymers and glycolide for the treatment of aneurism, we converted that license to an exclusive global license, and we recently licensed some additional patents. So I would say that the patent portfolio is robust, and it’s an area of focus and a resource for us, and we’ll continue to make it stronger both with internal and external I.P.

TWST: Are there strategic opportunities for this company using acquisitions, mergers, joint ventures or strategic alliances? If so, would you be looking at specific markets or functions, or even technology to fill in over the next several years?

Mr. McDermott: From a product perspective, we are building our capabilities and our infrastructure to develop everything we need internally. We don’t want to be in a situation where we are dependent upon our ability to source external products for our growth. So we would like to control our own destiny in terms of our new product portfolio. That being said, if we identify external technologies that we think are better than what we’ve developed or can contribute to our growth and shareholder value, we will actively evaluate those. Nellix would be a good example of that; so we are very open to partnering with other companies on new technology, but we’re not going to rely upon that for our growth.

In terms of other collaboration and partnership opportunities, I think there may be some of those as we expand into other markets, whether that’s in distribution or other collaborations. Our intent, again, would be to remain independent and build our own team and our own markets. There are going to be some places where it just makes sense to partner, and so we’ll evaluate all those on an individual basis.

TWST: What might be major concerns or risks facing Endologix right now, realizing that you rely on a single vendor for the supply of your specialized graft material? If that relationship fails or becomes comprised, do you believe you could make it with another?

Mr. McDermott: More broadly, I don’t think there is anything unique to Endologix with regard to risks. There are risks that are shared across Class III medical devices, which have a complex regulatory and clinical environment, and there is a lot more focus on price and margin compression. So we share as a category, issues and challenges, with all of the companies, but I don’t think there is anything really unique to Endologix in that regard. As it relates to PTFE graft material, I can’t comment specifically on the details of each of our key supplier components, but we feel that we have done a very good job at mitigating our supplier related risk. That’s an important area of focus for us.

“From a product perspective, we are building our capabilities and our infrastructure to develop everything we need internally.”

TWST: Do you see any large-scale economic, demographic or political factors that will affect Endologix in one way or the other?

Mr. McDermott: Again, nothing that would be unique to Endologix. Our reimbursement is in place, so I think there is always going to be pressure on the health care system to lower costs, and we appreciate that and we accept our responsibility in not just driving down the cost of the devices, but driving down the overall cost to treat the patients. People tend to focus on the price of the product, but in fact in many therapies including our devices and with these patients — if a device is very safe and effective and has very good long-term results with very few secondary interventions, the overall cost to treat those patients can come down dramatically. That type of cost savings tends to be where we focus our efforts. We want to have a competitive price, but we’re really not trying to be a price leader. We are trying to establish a leadership position in device safety and efficacy as well as ease of use.

Going back to your question, I don’t see any risks or issues that are unique to Endologix within our competitive set; in fact, there is a lot of talk about the challenges in some of the other geographic markets. For us, we’re not in a lot of those places yet, so it’s all upside. We’re not in a situation where we’re trying to backfill revenue declines because of soft pricing and other things; many of these international markets are untapped for us. So given our relatively modest market share position globally, we’ve got what we think are years and years of growth and expansion both from a product perspective and a geography perspective.

TWST: Perhaps you could tell us something about the background expertise of your management team.

Mr. McDermott: I got a very talented team, and of course I’m biased in favor of my team. I have worked with several of them for many years; you want me just to run through the whole team?

TWST: Your core team, your CFO perhaps.

Mr. McDermott: Our CFO is Shelley Thunen, and she is relatively new to the company. Shelley just joined us at the outset of the year. She has a long and successful track record as a CFO for medical technology companies. She also has been involved with
companies that have gone through significant growth, and companies that have transitioned from losing money to making money, so she has got a very good profile, a track record, is well-respected on the Street and is a nice addition to the team.

“\textit{This clinical area is also extremely rewarding; these patients are really sick and these are life-saving devices, so it’s a very serious type of technology with a lot of responsibility.}”

We have Bob Mitchell, who is our President of International. Bob actually came to the company with the Nellix acquisition. Bob was the CEO of that company and works primarily in Europe, really leading the development of our European sales and marketing organization, but also has responsibility for all of the other markets outside the U.S. He has a fantastic track record. Bob spent many years at Cook and was also at AngioDynamics; he’s just a very talented executive.

Joe DeJohn is our VP of U.S. Sales. Joe and I have worked together for many years; we worked together at Bard. He has built a great team; you see the results that he is putting up in a market with low-single-digit growth. Ruth Lyons is our VP of Marketing, also a very successful track record, most recently with St. Jude before joining the company a couple of years ago. Stefan Schreck, who we just recently announced is going to take a little bit of time off as our Chief Technology Officer, is still going to stay involved with the company. His experience goes back to near the inception of the company.

Just recently, a new addition to the team is a gentleman named Jim Machek. Jim is our VP of Research & Development, also great track record and background in cardiovascular devices, including Medtronic, where he spent 10 years in the endovascular business, so knows the space very well. Todd Abraham is our VP of Operations. He was previously with Edwards for many years as a Vice President of Operations there; he is fantastic. In fact, we’ve just now announced recently our plans to expand our headquarters, so we’ll be moving in about a year, and Todd has coordinated in managing basically a doubling of our footprint to support our continued growth.

Gary Sorsher is Head of Quality. Gary and I also had worked together in the past at Bard. He is a very, talented quality executive. We’ve had multiple inspections from both the FDA as well as other regulatory agencies outside the U.S., and have a very good track record for successful outcomes in compliance. Janet Fauls is our VP of Regulatory Affairs. Janet is amazing and has outstanding relationships with the FDA. Chuck Love is our VP of Clinical Affairs and also has a strong track record of success in medical devices. Dave Jennings is the newest member of the team. He just joined us a month ago as the VP of Human Resources. Dave will play a key role in helping to get the organization ready for our next wave of growth.

**TWST:** Good enough, that’s great.

**Mr. McDermott:** I can keep going and going, as I think it’s a very talented team, I’m fortunate to get to work with them every day.

**TWST:** You’ve been here for five years, coming on board as President and CEO in the spring of 2008. Why did you join this company? What opportunities or challenges did you see? Give us a personal report card.

**Mr. McDermott:** I joined in May 2008, but I actually had a history with the company before that, back when I was at Bard, all the way back to 1999. I was running the vascular business there, and we had entered into an agreement to acquire Endologix when it was an angel-funded startup. We were very intrigued with the platform at the time, and this is back in the earlier stages of the evolution of the EVAR marketplace, and we thought an EVAR device would be a good complement to the portfolio. So we entered into an agreement to buy the company, and we built a small sales and marketing team to introduce the first generation device into Europe, so in addition to becoming a shareholder with an option to buy the whole company, we had European distribution rights, so I got direct experience and exposure to the platform at that time. And although that was a very positive experience, the U.S. clinical study took considerably longer than it was anticipated, and the option to acquire the rest of the company expired, and we had a lot of other growth opportunities ahead of us at Bard and decided to pass and go do some other things.

So we had a relationship, and I kept in touch with the company and kind of monitored it from the sidelines, and then several years ago was approached by the board with the opportunity to join the company. I did a lot of diligence on the growth prospects and was very encouraged by what I saw, and so I took the job in May 2008. I’m pleased with our progress, but we’ve still got a lot of work to do, and there is a lot of growth ahead of us. So I’m happy with the quality of the team and I think we have accomplished a lot, but we’re really just scratching the surface on what the company can be.

**TWST:** Would you comment on the personal satisfaction that you’ve derived from developing a company like this?

**Mr. McDermott:** I love it. I mean, this is my hobby; this isn’t a job for me. I absolutely love what I do. This clinical area is also extremely rewarding; these patients are really sick and these are life-saving devices, so it’s a very serious type of technology with a lot of responsibility, and so you really feel good about the contributions you make and the technology that we’re developing. We really think we’re making a difference in the lives of AAA patients. This is really my sweet spot; I like companies this size because we can really build into a meaningful organization and take care of a lot of patients to really improve their lives. I’m very happy; I can’t image doing anything else.

**TWST:** For the long-term investors looking at the financial statements and annual reports for this company, what would you suggest are the one or two items, or the one or two sets of information that the investor should focus on to get insight into what you’re doing and where you’re going?

**Mr. McDermott:** I think there are a few things. I would take time to understand the core business, because it is a very healthy robust business with continued growth prospects. Then on top of that you’ve got what we believe is a very exciting new
product pipeline; a pipeline that we think can really change the landscape of the way AAA patients are treated and change the whole profile of the company over time. Then the last thing I would point to is the management team. This is a group of executives that has a track record for building successful businesses.

**TWST:** Do you feel that the current price reflects what you see as a stable long-term value to the company when compared to, first, the overall stock market, but second, relative to your perceived peers?

**Mr. McDermott:** I think we are fairly valued today, but we think that there is significant growth and appreciation in the value of the company in the years ahead.

**TWST:** How can Wall Street improve its perception or its understanding of Endologix? Do you feel that there are areas that are misunderstood or misperceived, or maybe company positions that lack insight?

**Mr. McDermott:** I think that the analysts that cover the company do a very good job. I don’t believe there are any big disconnects between how the world sees us and how we see ourselves. So I think the guys and women that cover us now do a very good job; we’re fortunate to have them.

**TWST:** As for strategic proprieties for the remainder of 2013 into 2014, what’s on top of the list?

**Mr. McDermott:** For the rest of this year, big important items are, we are going through a process for our Ventana device, evaluating our clinical experience and also developing some design enhancements. We have announced that we would provide an update on our plans for Ventana by the end of this year, so that’s an important initiative for us; that’s a product that we think that has a lot of growth potential.

With Nellix, we’re in our limited market introduction in Europe in a small number of centers and working with the FDA and hope to get our IDE approved by the end of this year, so that’s obviously a major focus for us. We also have a product line extension for AFX that we plan to initiate a limited market introduction in the U.S. by the end of this year, and the continued execution and penetration of our percutaneous EVAR program. So those will be our primary focus areas for the second half, and those will transition into 2014. We will transition in Europe, for example, to more of a full market introduction of the Nellix device over time.

We should be enrolling our U.S. clinical trial with Nellix next year as well as running a postmarket clinical trial with Nellix outside the United States. We expect to restart our clinical work with Ventana next year as well, and we will have a full year of growth from a new product line extension related to AFX. So we have a busy 2013, 2014 and actually 2015 and 2016 and 2017, too. We’ve got a very full pipeline — that doesn’t even talk about the new markets we’re going to expand into. I’m being fairly product-focused at this point, but we’ve got a lot of opportunity.

**TWST:** If you were sitting down today with a potential investor at the end of a road show and making a summary statement, what are the points that you would want him to take from that show?

**Mr. McDermott:** We have a strong core business, a new product pipeline with tremendous growth and an experienced proven management team.

**TWST:** Thank you. (KL)
Mr. Wolcott: BSD Medical was founded in 1978 and is listed on Nasdaq under BSDM. We have pioneered medical device systems for the treatment of cancer, specifically by utilizing heat therapy. We have two segments to our business. The first is hyperthermia, which is a treatment modality that heats cancer to approximately 43 degrees centigrade. It causes changes in the cell physiology and dramatically increases the effectiveness of radiation and chemotherapy.

The second key modality we have is in the area of thermal ablation. We use microwave energy in both of our technologies; however, with our ablation therapy it is at a much higher temperature, 100 degrees centigrade or more. Our microwave ablation therapy, MicroThermX, has received 510(k) clearance from the FDA. MicroThermX is a standalone treatment, which uses microwave energy to destroy cancerous tissue. BSD Medical is fundamentally focused on thermal energy for oncology, because heat does amazing things for the treatment of cancer.

TWST: What are some of the advantages of hyperthermia and ablation treatment, and how much physician training is required?

Mr. Wolcott: Let us start with ablation. Ablation is a standalone treatment. A vast majority of the time it begins with a simple skin puncture. Utilizing imaging, the physician punctures the tumor with a microwave-emitting antenna. Over a 10 to 15 minute period, the microwave energy destroys the tumor. After withdrawing the antenna you can simply put a Band-Aid on the patient, and they go home the same day. This is radically different than many other surgical treatments by more than 50% using hyperthermia in conjunction with radiation and/or chemotherapy. There are varying degrees of expertise required, but hyperthermia is very straightforward when compared to many other hospital procedures.

TWST: What about pricing?

Mr. Wolcott: Regarding pricing, both treatment modalities play directly into the economics of medicine in the future. Under the Affordable Care Act, less money will be available for many diseases. Ablation is a minimally invasive procedure compared to open surgery and much less expensive. You can perform an ablation treatment or a hyperthermia treatment for a few thousand dollars, a fraction of the cost of many other oncology procedures. With an aging population, the demographic that is most frequently afflicted with cancer, cost is already a very important factor.

TWST: What were the tools prior to your tool set, and what were the needs that were not being addressed?

Mr. Wolcott: Chemotherapy, radiation and surgery have been the primary tools. When adding hyperthermia to either radiation or chemotherapy you get a dramatic difference in patient outcomes for varying diseases, because it helps increase the delivery of the drug and/or increase the effectiveness of the radiation due to increased blood perfusion and higher levels of oxygen.

Ablation can offer an alternative to either surgery or chemotherapy. Destroying a tumor with microwave energy and sending the patient home the same day as opposed to a surgical treatment that may keep the patient in the hospital for a much longer period is a dramatic improvement for patients, doctors and hospitals.

TWST: You recently announced results for the third quarter ending May 31. What were some of the highlights? And, for the longer-term investor looking at your financial statement and reports, what would you suggest as one or two items to focus on to gain insight into what BSD Medical is doing and where you’re going?

Mr. Wolcott: We had a historic milestone development for BSD last quarter, and that was the signing of a Master Distribution Agreement with a major distributor in the region.
Agreement for our ablation system, MicroThermX. The agreement is with Terumo Europe NV. Terumo Corporation, incorporated in 1921, is the parent company of Terumo Europe and does approximately $5 billion in sales worldwide. The distribution agreement covers 100 countries, from roughly Russia on the North to Morocco on the South. The potential market size in these countries for thermal ablation is estimated to be over $1 billion in annual sales.

“There is always M&A activity on the radar, which would potentially bring other complementary and synergistic products to BSD, both in ablation and hyperthermia.”

Terumo has a tremendous reputation in the medical business. They evaluated all of the ablation systems that are available in the marketplace. They chose to distribute our product, MicroThermX. The agreement with Terumo Europe NV has minimum purchase requirements and is a multiyear agreement. It is very attractive for both companies economically. Working with Terumo further validates our technology and is a very significant development for BSD Medical. We also believe the agreement is going to make a big difference for us economically and shorten the road to profitability.

TWST: When looking at margins for this company, what do you see as the key factors or critical variables that will influence margins over the next two to three years?

Mr. Wolcott: While competition always affects margins, we think we have an advantage with the design of our product. It is the finest with regard to groundbreaking technology, yet inexpensive to produce. Also, as in most businesses, as we increase volumes with arrangements like Terumo, the margins we believe will be incredibly attractive.

TWST: What’s on the agenda? What are the priorities for the next 12 to 24 months? What can make that time frame exceed expectations?

Mr. Wolcott: We want growing revenues, expanding margins and to reach sustained profitability. We are going to do that by executing on distribution agreements like Terumo and are going to try and expand our collaboration efforts distribution-wise with major companies. We want to grow the adoption of MicroThermX domestically and abroad. We have seen a strong and renewed interest in hyperthermia in Asia, and we are going to explore those markets more aggressively than we have in the past. We have some new distribution arrangements in South Korea and Taiwan, particularly. In summary, MicroThermX adoption, expanding hyperthermia in Asia, and increased financial performance are the things we are going to concentrate on short-term.

TWST: How about M&A? Are there some possible deals going on? Are you expecting deals down the road?

Mr. Wolcott: Obviously, we cannot comment on M&A activity. Collaboration with companies like Terumo naturally brings that kind of expectation from investors. Our mission for the shareholders right now is to grow the value of the business. That is what we’re trying to do at this point in time.

There is always M&A activity on the radar, which would potentially bring other complementary and synergistic products to BSD, both in ablation and hyperthermia. We are always exploring that kind of activity from a synergistic viewpoint, and we will continue to do so.

TWST: You mentioned ObamaCare earlier. Do you see any large-scale economic, demographic, political factors that will affect you one way or the other?

Mr. Wolcott: We think the Affordable Care Act will have a positive effect as health care providers and patients look for less invasive, more cost-conscious, effective cancer treatments. The aging demographic worldwide will also have an impact on our business. Innovation is important, but economically your products and your technology must fit into the economic picture.

TWST: Can you give us an idea of the intellectual strength of the company? How strong is the IP portfolio?

Mr. Wolcott: Our product line is centered on radio frequency and microwave energy. BSD was founded in 1978. We have probably been involved in the field longer than anyone. We have a strong patent portfolio. We feel we are in a very enviable position with regard to intellectual property.

TWST: Tell us about the background and expertise of your management team.

Mr. Wolcott: The new senior management of BSD that has been assembled over the past few years has well in excess of seven decades of experience in both large medical device companies and medical device startup environments. I think it is an important blend in a situation like this, where we are trying to achieve profitability and exploring new products like MicroThermX.

Many of us know each other through other startup medical opportunities. We fit together well and complement each other with our strengths and weaknesses. We believe in ownership, having a direct impact on the business. The people component of a business to us is important. We like each other very much and think we have a very strong team in place.

TWST: What caused you to join this company? What were the challenges and opportunities that you saw? And then finally, as a personal report card, have you met the goals that you set for yourself?

Mr. Wolcott: I first heard about BSD in 1982. I’ve been in the medical business a long time. I have always liked the noninvasive or less-invasive aspect of medicine. As a trend, things continue to move toward this practice of medicine.

I was particularly attracted to BSD’s ablation technology when I joined the company in 2009. Although it has been challenging over the past few years, especially in a capital constrained environment, I still believe it’s an exciting opportunity, and it remains an opportunity I strongly believe in. You always want things to happen more quickly, and I am my toughest critic, but I feel like we have made a lot of progress, especially in the past year or so, culminating with our recent Terumo Europe NV announcement.

TWST: How is the financial community responding to
the company these days? Are there any common questions or concerns being raised by investors concerning your operational strategies? What’s going on there?

Mr. Wolcott: Investors like to see things happen more quickly, and their expectations are high. They would like us to move more quickly toward profitability. One area where there may be some misperceptions is the lengthy sales cycle for capital equipment. It is one of our challenges in the business. While we have tremendous upside with the technologies that we are involved in, if you talk about the downside, it is capital equipment and long sales cycles.

We also face a tough regulatory environment around the world nowadays. I think it can be difficult if you are not part of the sausage making to have a good read and accurate perception about the challenges in our business. We admittedly have difficulty explaining some of these factors from time to time.

TWST: What might be some of the barriers for this company as far as gaining markets, gaining customers? How will you resolve getting your foothold expanded in the overall cancer therapy market?

Mr. Wolcott: One of our biggest challenges is we are a small company. We are not Johnson & Johnson, C.R. Bard or Boston Scientific. Therefore, not being well-known, particularly in ablation, is sometimes a challenge. However, now that we have agreements like Terumo in place, we will have more power and sales reach.

TWST: Would you comment on the personal satisfaction that you’ve derived from developing a smaller company like this and leading it forward?

Mr. Wolcott: I’ve been part of the medical business since 1968 and more than half of that time has been spent in startup companies or businesses with challenges. That’s what I enjoy. Many times you are building something from nothing. Taking a patented idea and developing it and nurturing it into a technology that can revolutionize medicine is rewarding. When you take a revolutionary technology and you personally see how patients are positively affected by it, the experience is very compelling.

TWST: As you look at the shareholder universe, give us a description of what you see. How is that base changing; how has it evolved?

Mr. Wolcott: I think now and over the years, our shareholder base has been mostly retail investors, which are great and have been big supporters of BSD and our technology. We also know the importance of developing a good base of long-term, actively managed, institutional shareholders. We believe we are in a position to start expanding our shareholder base because of positive developments, including our master distribution agreement. Having more institutional investors involved in BSDM, as well and getting on the medical device sellside radar will be good for all constituents involved.

TWST: In conclusion today, what is the summary statement that you would present to an investor if your task were to provide the assessment for an investor to make the decision to buy in? What are those strengths and highlights that you feel compel that decision?

Mr. Wolcott: We have superior technology for the thermal treatment of cancer. We are in a strong competitive position in a large and a growing market. Cancer remains the second-leading cause of death in the United States. We are poised to benefit from the developing trends in health care, moving toward more cost-efficient and less-invasive procedures. We have the razor/razorblade disposable component to our MicroThermX product, which enables us to enhance revenue and margins over time. Finally, we have and are pursuing new collaborative arrangements with companies like Terumo, which can potentially be game changers for BSD.

TWST: Thank you. (KL)
COMPANY INTERVIEW

diaDexus, Inc. (DDXS)

BRIAN WARD has served as President and CEO of diaDexus, Inc., since September 2011. Since September 2010, Dr. Ward has served as Chief Operating Officer at On-Q-ity Inc., a private oncology diagnostics company. Prior to that, Dr. Ward served as its Executive Vice President starting in May 2008, in which capacity he had primary responsibility for research and development process. Since March 2008, Dr. Ward has also served as President of Advantage Genomics, Inc., a private company that provides strategic and tactical consulting services to biotechnology organizations with particular emphasis on personalized medicine diagnostics. From February 2007 to February 2008, Dr. Ward served as Senior Vice President, Development at Genomic Health, Inc., a public company focused on genomic-based oncology diagnostics, in which capacity he was responsible for overall management of all product development activities. From 1996 to 2006, Dr. Ward served in various capacities at Myriad Genetics, Inc., a public molecular diagnostic company, most recently as its Senior Vice President, Medical Operations from January 2002 to October 2005. Dr. Ward received a B.S. in zoology from the University of Wisconsin and an M.S. in human genetics and a Ph.D. in biochemistry, biophysics, genetics from the University of Colorado Health Sciences Center.

SECTOR — HEALTH SERVICES

AXD611) TWST: Let’s begin with a brief historical sketch of diaDexus and a picture of the company’s operations.

Dr. Ward: Yes, thank you for speaking with me today. diaDexus identifies the hidden risk of heart attack and stroke, above and beyond traditional cholesterol measurements. We have an FDA-approved test kit called the PLAC Test that identifies the hidden risk of heart attack and stroke. As you know, 50% of all people that have a heart attack or stroke have normal lipid levels, and this represents those individuals who have a hidden risk. Currently, that’s a U.S. addressable market of over 36 million lives. We’ve had strong financial performance over the last 11 quarters with consecutive year-over-year revenue growth. Last year, in 2012 versus 2011, we had a 27% year-over-year revenue growth. So we have a strong, growing base business with substantial growth drivers, and we look toward identifying the hidden risk of heart attack and stroke.

TWST: What are the market dynamics? What are the underlying growth factors, and where does diaDexus fit in with respect to that overall market?

Dr. Ward: Yes, good question. So we have a new selling model over the last two years that we developed. We realize that the real benefit of cardiovascular biomarker diagnostics is in prevention, so currently the PLAC Test is offered in association with other cardiovascular markers for advanced lipid profiling to primary care physicians so they can identify people who are at increased risk of cardiovascular disease and take more aggressive treatment options.

TWST: Your PLAC Test measures Lp-PLA2, the vascular-specific inflammatory enzyme blamed for the formation of rupture-prone plaque. Would you comment on this test and its relationship to the GlaxoSmithKline inhibitor study and where it’s at? Where does it fit in in relation to the ongoing Phase III clinical trials?

Dr. Ward: Yes, you’re correct. The PLAC Test does measure Lp-PLA2, which is associated with instability and rupture-prone plaque. So the higher the Lp-PLA2, the higher the risk of having a ruptured plaque, which would throw off a clot, a thrombosis, and which could lead to heart attack or stroke.

GSK has two Phase III clinical drug trials in progress right now with a drug called darapladib. Darapladib is a specific inhibitor of Lp-PLA2. So it really knocks Lp-PLA2 out, and the thought here is that if you knock out this molecule, you could take a rupture-prone plaque and stabilize it, and maybe even make it regress to a more stable form. We have measured Lp-PLA2 on every patient in these Phase III clinical trials, and if the drug is successful and if a companion diagnostic is required, we have the rights to distribute that companion diagnostic worldwide.

TWST: What is the market size for the PLAC Test, and what is its competition?

Dr. Ward: The market size in the United States alone is that 80 million people have moderate to increased risk of cardiovascular disease in the United States, so that’s a huge market. Of that, about 36 million of those 80 million are actually in the health care system with Medicare coverage and/or private insurance companies. So that’s our addressable market.

As far as competition goes, there’s no direct competition for the Lp-PLA2 PLAC Test. It is run in association with other advanced lipid profiles, and each one of those markers contributes to understanding the underlying risk of cardiovascular disease. I’d like to point out, though, that the Lp-PLA2 is the most specific of those markers, and it can lead to actions that the physician can take.
**COMPANY INTERVIEW — DIADEXUS, INC.**

**TWST: Is cash or capital a limitation on diaDexus as it looks at not only its own growth opportunities, but other opportunities for merger, acquisition and partnerships?**

**Dr. Ward:** Yes. As I mentioned before, we’ve had really three years of very strong growth, and we’re guiding toward another year of strong revenue growth. Our guidance as of May 6 was $24 million to $25 million for 2013. Over the last several quarters and the last couple of years, our net loss per share has decreased dramatically, and now it’s a couple of pennies per share. Cash, current cash balance at the end of the Q1 of 2013, was $13 million, of which $5 million of that was a loan at 5.25%. So for operational expenses and also for the initiation of our pipeline, we believe we have sufficient operating capital for at least the next year.

**TWST: Are there any inflection points with regards to cash or capital being required over the next few years?**

**Dr. Ward:** Right. Well, diaDexus’ business model really has three prongs to our attack. Number one is to grow our base business, both here and throughout the world. Number two is our relationship with GSK and the potential companion diagnostic. And finally, we are in the midst of creating a viable cardiovascular pipeline for cardiovascular biomarkers that can go through regulatory approval. While we believe we have initial capital available to begin that process, if we find an exciting biomarker or we find an exciting opportunity, there’s always a potential that we would need to raise capital in the future, but for the immediate future, we think that we’re OK.

**TWST: Where would you expect this company to be in three years, and what might be some milestones to watch for?**

**Dr. Ward:** Well, I think — the first milestone along the way is that we are working with the FDA to get our activity test launched in the United States. Currently we have a test in the United States called the mass test, and we would like to get another formulation of that approved in the United States, and so that will open up the market for us. Looking down three to five years, I think we’re looking at a strong and growing base business. We’re looking at creating a strong and viable pipeline, and then, of course, no one can predict whether or not darapladib will be successful. So we kind of look at our business as a diagnostic business with an FDA-approved test kit that we sell through specialty laboratories to physicians as our base business, which is growing strong, marching toward profitability with an upside potential for new products and the potential of darapladib.

**TWST: Do you have the right management team, skill sets, bench strengths, to meet these opportunities?**

**Dr. Ward:** Yes. Well, we have a brand-new management team in place. The management team really came together starting about two years ago. Prior to that, I was on the board of directors at diaDexus for a little bit, and I came on in September of 2011. I brought with me a very experienced team of four individuals, all who have experience in developing and commercializing diagnostic products. My Chief Business Officer is Mike Richey, who came from Tethys and Chiron. My Chief Financial Officer is Jean-Frederic Viret, who came from XDX and Anesiva. Emi Zychlinsky is our Chief Technical Officer, who came from Hitachi and MAST Immunosystems. And then to round out the team, our Vice President of Medical Affairs is Dr. Robert Schott, who is a practicing cardiologist and a biomarker specialist.

These people are, as I say, extremely experienced in developing and commercializing diagnostic products, so I’m very comfortable we have a strong team. We may add one or two more people to this team over the foreseeable future, specifically in the science arena, but we’re very happy with our selling model, which is to sell through cardiovascular specialty laboratories to primary care physicians for prevention of cardiovascular disease.

**“Currently we have a test in the United States called the mass test, and we would like to get another formulation of that approved in the United States, and so that will open up the market for us.”**

**TWST: At this point, how could the investment community better understand diaDexus? Are there any misperceptions that you hear, or perhaps assumptions in the marketplace or in the competitive field that you hear with which you disagree?**

**Dr. Ward:** Well, I don’t really disagree with the perceptions of the market. I think that what’s been hampering diaDexus is really lack of perception. Prior to changing out the executive team and moving in the direction towards a new selling model, diaDexus was a little bit stagnant. Now we have a dynamic, growing base business. We have opportunities for an upside potential with GSK and we’re building a pipeline. So what that means is we really have an exciting story, and I think the stock market is beginning to respond to that, and as we build shareholder value, we expect that our enterprise value will continue to increase and the stock price will continue to increase. So what’s really important is we get out the message that we have really a viable company moving in the right direction.

**TWST: What is the long-term vision? When you look at the ultimate enterprise, what does that ultimate enterprise look like?**

**Dr. Ward:** I think to penetrate the market of 36 million people in the United States is a tall order. We have our goals set up for the next couple of years, but currently over a million people a year are receiving this test, and so what we’d like to do is of course grow that exponentially, and over the coming years, as physicians and patients become more and more attuned to preventative measures, I think our PLAC Test will continue to grow in a very strong manner.

**TWST: Today, what is the summary statement for an investor? If your task were to provide the assessment tools for an investor, what would be the strengths and highlights that you believe present the positive investment decision to buy in?**

**Dr. Ward:** Absolutely. So the PLAC Test finds the hidden risk of heart attack and stroke. 50% of people who have a heart attack or a stroke have normal lipid levels, so if you have two or three risk factors for cardiovascular disease, an individual should consider having
advanced lipid profiling to understand the hidden risk. diaDexus has long-term growth potential through our pipeline expansion. We’re excited about our partnership with GSK and its two Phase III clinical drug trials. And of course, our base business is focused on primary care physicians and prevention of cardiovascular disease in their practices.

The total market is 36 million. We have substantially core business drivers that are in place and our partnerships with cardiovascular laboratories. Our year-over-year revenue from 2011 to 2012 grew at 27%, and our guidance as of May was to $24 million to $25 million this year, and our first-quarter revenue was a solid quarter with $5.6 million in revenue. So it is a strong, growing base business with a relatively new management team driving into a market where prevention of cardiovascular disease is essential.

TWST: Outstanding. Anything you’d like to add; anything we’ve missed?

Dr. Ward: I think we’ve covered all the highlights, and I appreciate your time and your insightful questions, and I’d tell investors to stay tuned and even to take a look at this really remarkable company.

TWST: Thank you. (KL)

BRIAN WARD
President & CEO
diaDexus, Inc.
349 Oyster Point Blvd.
San Francisco, CA 94080
(650) 246-6400
(650) 246-6499 — FAX
www.diadexus.com