


**CEO INTERVIEWS**



**Larry Heaton II**  
President and Chief Executive Officer  
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**Patrick Johnson**  
President and Chief Executive Officer  
**Pro-Dex, Inc.**  
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**Charles A. Green**  
Chief Executive Officer  
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**Mark Throdahl**  
Chief Executive Officer  
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**Gilbert Achermann**  
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President and Chief Executive Officer  
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Chairman and Chief Executive Officer  
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**Kelly Olsen**  
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**FOCUS ON MEDICAL TECHNOLOGY STOCKS**


**ROUNDTABLE FORUM**

## Focus turns to fast-growing small-cap med-tech firms

**L**arge-cap medical tech stocks have performed extremely well over the last year, but while smaller companies have caught up to some extent, they still lag their larger competitors. Where are the richest opportunities to be found? On October 21, 2003, *Wall Street Reporter Magazine* hosted a medical technology roundtable on investment opportunities in that sector.



**Christopher C. Cooley, CFA**  
Senior Analyst and Vice President  
**FTN Midwest Research**



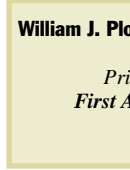
**Peter Gombrich**  
Founder, Chairman and CEO  
**Molecular Diagnostics**



**Jan David Wald**  
Vice President of Securities Research  
**A.G. Edwards & Sons**



**Patrick L. Johnson**  
President and CEO  
**Pro-Dex, Inc.**



**William J. Plovanic, CFA**  
Principal  
**First Albany**



**Bradford E. Siff, M.Eng., MBA**  
Chairman, President and CEO  
**Biowave Corp.**

Participating from Wall Street: Jan Wald, medical instruments analyst at A.G. Edwards & Sons; Chris Cooley, medical products analyst at FTN Midwest Research; and Bill Plovanic, medical equipment and supplies analyst at First Albany. Specific disclosures regarding each issue discussed can be found in the analysts' recent reports; available upon request.

Participating from the corporate sector: Brad Siff, Chairman, CEO and President of Biowave Corp.; Patrick Johnson, President and CEO of Pro-Dex Inc.; and Peter Gombrich, Chairman and CEO of Molecular Diagnostics Inc.  
**(Closing price is as of October 31, 2003)**

**WSR:** Bill, could you kick off the discussion? Are there any particularly interesting areas in terms of new research, new products, and important things going on in the companies you follow?

**PLOVANIC:** Actually, our coverage is pretty focused. I cover orthopedic and neu-

rotechnology companies, and if you look at the future where the exciting research is going, (at least in my coverage sectors), it is more focused toward the neurotechnology names. These devices utilize pacemaker-like technology; they are trying to treat unmet clinical needs and solve some of the problems with these devices. So, we believe there is a big opportunity in terms of market opportunity for these names.

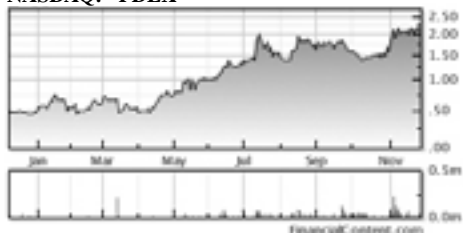
**WSR:** Patrick at Pro-Dex Inc. (NASDAQ: \*PDEX \$1.62), can you give us a brief introduction about your company? You do a lot of work in miniature motors and motion control devices. Where do you see interesting things at this time?

**JOHNSON:** Our products have two operating subsidiaries. First, Micro Motors, which specializes in the design and manufacture of miniature rotary drive systems (primarily used in medical and dental orthopedic end pieces). Second, is our Oregon Microsystems (OMS), a subsidiary that specializes in embedded multi-axis motion control. These are basi-

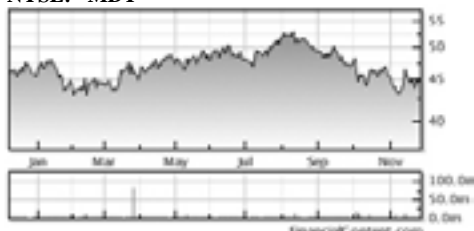
cally products with XY axis finding capability. What we are really seeing is everything moving towards minimally invasive: things are getting smaller, more precise, and more remote. And I think Pro-Dex is well positioned for that with a combination of micro motors, rotary drive system expertise, and OMS's expertise in motion control. But one project we've recently worked on that is in clinical trials in the United States right now, Medtronic Inc. (NYSE: \*MDT \$45.57), is running clinical trials on their final implant, which is an artificial final disk implant that will take the place of traditional vertebrae fusion. So, we are really excited about those clinical trials and the drive system that is key to putting in that implant.

**WSR:** *Certainly in terms of electronic technology, everything is getting more and more miniaturized. That must be having a*

**NASDAQ: \*PDEX**



**NYSE: \*MDT**



*significant impact in terms of the direction for your company.*

**JOHNSON:** Absolutely. In that, we've seen a major restructuring in the semi-conductor industry in the last few years, with manufacturing making a global geographic shift as well as the shift from 200mm to 300mm wafer manufacturing. There's a lot of opportunity on the semi-conductor side, but we are also trying to get that subsidiary focused into the medical industry where there also is a lot of application for the motion control product.

**WSR:** *Jan, how does the investment landscape look in terms of the focus in your companies?*

**WALD:** I guess we focus on three particular areas, cardiology, neurology, and orthopedics. I think the two most exciting areas are cardiology and neurology. As Bill said before, I think there are some innovations coming in neurology, both on the electrical stimulation side and also on the catheter-based delivery side, especially for treating brain aneurysms. On the cardiology side, I think there are a couple of things that are going on that are very interesting. I think if you look at drug-eluting stents, most of the interventional cardiology

**“There are some innovations coming in neurology, both on the electrical stimulation side and also on the catheter-based delivery side, especially for treating brain aneurysms. On the cardiology side, I think there are a couple of things that are going on that are very interesting.”**

gists now believe that those are sort of in the market and passé. They've started to focus on something called vulnerable plaque, an area where if you look at the number of people who die from heart attacks every year, about 70% of those are due to what are now being called vulnerable plaques. So, being able to diagnose what plaque is vulnerable and then to treat it is something that a lot of work is being devoted to, both in terms of large and small companies. And then with regard to atrial fibrillation, which seems to be a never-ending story in cardiology, there are a number of new interesting ablation techniques. These are energy sources, in fact, that are coming down the pipe that I think will be quite interesting for the physicians to look at and to examine with the clinical data in hand.

**WSR:** *Brad, if you can give us a brief introduction to some of Biowave Corp.'s programs?*

**SIFF:** By the way, I have to agree with Bill and Jan: I think in the neurotechnology device space, there's a huge opportunity. Biowave has developed a proprietary, minimally invasive pain treatment therapy. The device produces a patented signal which is delivered through a proprietary percutaneous electrode array. Our clinical studies show that a 20-minute treatment provides patients with an 80% reduction in pain and a significant increase in range of motion that lasts for at least 24 hours. In the whole pain market space there's not one pain treatment modality that is a panacea; there is a need for a treatment that is efficacious with no side effects, that is minimally or non-invasive, and that can be delivered at low cost. Biowave meets this need.

**WSR:** *Chris, in terms of target topics or specific products, what do you see that's important right now?*

**STOCKS DISCUSSED**

*(Price close of October 31, 2003)*

- Advanced Neuromodulation Systems Inc. (NASDAQ: ANSI \$41.00)
- Alcon Inc. (NYSE: ACL \$55.11)
- Biomet Inc. (NASDAQ: BMET \$35.86)
- Boston Scientific Corp. (NYSE: BSX \$67.72)
- Cooper Companies Inc. (NYSE: COO \$43.45)
- Cyberonics Inc. (NASDAQ: CYBX \$27.35)
- Guidant Corp. (NYSE: GDT \$51.01)
- Medtronic Inc. (NYSE: MDT \$45.57)
- Molecular Diagnostics Inc. (OTC.BB: MCDG \$0.22)
- Pro-Dex Inc. (NASDAQ: PDEX \$1.62)
- Smith & Nephew Plc (NYSE: SNN \$80.07)



**COOLEY:** Here at FTN Midwest Research, my coverage primarily fixates on both the cardiac space as well the ophthalmology. On the cardiac front, I would go to what Jan previously mentioned about both AF and also with vulnerable plaque, and I would also indicate big opportunity there as well, longer-term, in the peripheral vascular segment. In ophthalmology, we've been fixated primarily on the local drug delivery system, and of course associated pharmaceutical agents to treat back-of-the-eye sight-threatening diseases. These are diseases such as macular degeneration, diabetic retinopathy, and posterior vitreous detachment. We find the prevalence rate (just over six million people in states annually) ticking

**“The most successful plays are the ones that have been purchased and their products are still two or three years away from market. But having said that, the orthopedic companies in general, you could say, are a little more mature market in valuation.”**

away. As you move to developing therapies on that front — that's really our key area of focus.

**WSR:** *Peter, Molecular Diagnostics Inc. (OTC.BB: \*MCDG \$0.22): Could you highlight some of the key screening programs that you are developing?*

**GOMBRICH:** We are on the outside of the area that Jan, Chris and Bill are focused on. We have taken a step leveraging research and working that into the genome project, and basically have automated a vehicle for looking at specific proteins developed in cancer and pre-cancerous conditions. And we do so with a fully automated platform. As with an antibody assay, it looks at specific proteins. The area that we are far along, in regards to the clinical trial, is in the area of replacement of the capsular. Specifically in med areas, the way this is done now is a very subjective test where someone looks under a microscope and looks at the physical characteristics, the changes. The genome program years ago identified cer-

### Christopher C. Cooley, CFA

*Christopher C. Cooley, CFA, a Vice President, joined the Research Department of Midwest Research in March of 2001 as an analyst specializing in medical devices and hospital supplies. Mr. Cooley was most recently employed as an analyst at SunTrust Equitable Securities, the wholly owned investment-banking subsidiary of SunTrust Bank, from March of 1998 to March of 2001. Prior to his employ with SunTrust Equitable Securities, Mr. Cooley was employed by Morgan Keegan & Company, Inc., from June 1994 to February 1998, providing fundamental analysis of health care companies. Additionally, Mr. Cooley was employed as a futures trader for Cargill, Inc. from 1990 to 1992, as well as having had a collegiate internship with Dean Witter.*

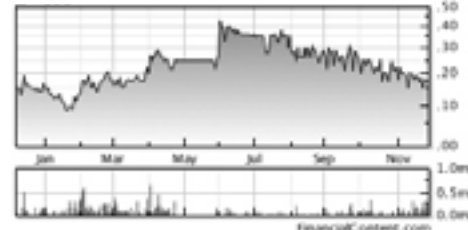
tain proteins that over- and under-expressed themselves in the cell prior to the time that they became cancerous, and basically we've developed an antibody assay, consisting of a number of probes with a fluorescent tag. And we've looked at this as a complete system; at both the

cytometer as well. That's the area that Molecular Diagnostics is focusing in on. We've also identified some other proteins, other cancers, beyond certainly the cervical area, but the company right now is focusing virtually all of its resources on the cervical space.

**WSR:** *Bill, in terms of the stocks that you follow, the stock market has done a little better since the spring and certainly a lot of medical stocks received attention. How do you feel about the investment outlook at this point?*

**PLOVANIC:** I really think you need to

OTC.BB: \*MCDG

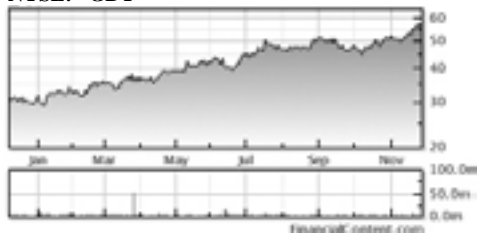


proteins, with assay (with a very sophisticated software algorithm) and using multiple platforms — one that looks at specific proteins out of slides, like a pap smear. You have a fully automated platform for doing it, which we also do in a flow

### SUMMARY

Many exciting opportunities remain undervalued in the medical technology field, especially among small companies working to fill unmet clinical needs. However, analysts and investors alike have been reluctant to focus on these smaller names until recently. While it is still difficult for such companies to raise cash, the capital environment has improved over the last six months. Meanwhile, larger players are pushing acquisition talks forward in order to maintain their own growth rates. In the absence of ready capital, many small-cap companies have pursued strategic partnerships; such relationships have allowed products like Molecular Diagnostics' (OTC.BB: MCDG) cervical cancer assay tech to reach potentially global markets. Areas of special interest include cardiology, ophthalmology and neurotech, where privately held Biowave's pain-blocking implant has achieved significant clinical results. Despite some innovation in orthopedics like artificial spinal disc driven by Pro-Dex (NASDAQ: PDEX) micro motors, the orthopedic area has matured and should be fairly valued until the next generation of indications hits the market.

NYSE: \*GDT



NYSE: \*BSX



NYSE: \*COO



segment investment outlook by the different markets that we look at, whether it be orthopedics or neurotechnology; the other analysts can comment on cardiology and the other spaces. But I think as you look at orthopedics in general, it is more of a mature market, except for artificial discs. We have not talked about artificial discs, however, the most successful plays have been purchased and their products are still two or three years away from market. But having said that, the orthopedic companies in general, you could say, are a little more mature and market valuations have run up significantly here, leaving the names more fairly valued in our opinion. As a result, we've actually downgraded a number of

the smaller names, as they tend to reach the higher end of their trading range, over the last couple of years. On the flip side, as you look at the neurotechnology names, these are the types of companies where the potential is enormous, and as they continue to move forward with new indications, it will continue to enlarge their overall potential. So while some of these stocks have some pretty high valuations at this point, considering the enormous potential, we believe that they can keep going. In summary, orthopedics has had a heck of a run, and we think most of them are pretty fairly valued, based on historical metrics. And then looking at the neurotechnology space, we think that they've run pretty well also, but long-term I think there's a lot more upside to those names. So, we keep a "buy" on the group. But again, remain long-term focused on the neurotechnology names but believe near-term, these stocks are becoming fully valued as well.

**WSR:** Jan, in terms of the investment outlook, how do things look at this point in the cycle?

**WALD:** Well, just going on with what Bill was saying, I think we view this space as almost fairly valued at this time. The large-cap companies (at least in our universe) have made nice moves over the last year. Small caps have caught up to some degree. We still think that there is some room in there to maneuver. One of the things that intrigues us about the coming 12 to 18 to 24 months is that from an investment perspective, the large-cap companies have an incredible amount of cash on hand. If you look at Medtronic, they said in their analyst meeting a couple of weeks ago that they had — if they don't make any acquisitions until 2008 — about \$10 billion in cash. Guidant Corp. (NYSE:

\*GDT \$51.01) and Boston Scientific Corp. (NYSE: \*BSX \$67.72) are going to throw off a lot of cash as well. What they do and how they deploy that cash is of interest, and likely they will be inserting it into smaller companies. So, from our perspective, the large cap space is fairly valued and the small cap space has moved, but there is probably some upside there as well. I agree with Bill that the orthopedic space has moved pretty nicely and so they are close to being fairly valued. The opportunities in neurology and in the neuro space are so large that even though the companies keep approaching fair value, the opportunities in some sense outweigh evaluations, at least in our perspective, and that leads to us continuing our "buy" recommendations on that part of the space. In cardiology, it looks to us as if the smaller-cap names have some maneuverability, whereas the large caps don't.

**WSR:** Chris, what is the general investment outlook from your viewpoint?

**COOLEY:** Roughly over the last 12 to 18 months we have seen very nice premium evaluations put into most of the med-tech companies who are defensive in this type of market. But within the ophthalmology space, we have been trying to fixate primarily on companies that are expanding out of the existing markets: geographical expansion, product launches, that seem to extend the life cycle of the product, as well as these companies that are targeting the liver disease. That kind of helps propel those evaluations, and if you look at it over the last five years, it is kind of a peak-to-trough multiple basis. Many of these companies in the mid-to larger-capital arena will remain at or below the historical.

**WSR:** Are there any specific companies you would like to highlight?

**COOLEY:** Within the ophthalmic space, I think I will focus in on two primarily. In terms of the smaller to mid-cap plays, one would be the Cooper Companies Inc. (NYSE: \*COO \$43.45). They are leading the industry in specialty lenses as well as a large player in women's health. The company is currently launching new products outside of both the U.S. and Europe into Japan, a market that here-

**Peter Gombrich**

Mr. Gombrich is the founder of Molecular Diagnostics as well as InPath, LLC, and has more than 30 years of experience in the health care industry. He founded AccuMed International, Inc. in 1994 and served as its chairman, president and CEO until 1998. Previously in 1982, he founded Clinicom, a health care information systems company. In 1976, Mr. Gombrich co-founded St. Jude Medical, a world-renowned life support medical device company, and previous to that established the sales and marketing department at Medtronic Inc. Mr. Gombrich has a Bachelor's degree in electrical engineering and an MBA from the University of Denver.

**Jan David Wald**

Dr. Jan Wald joined A.G. Edwards in June 2000 and focuses his research efforts in the medical technology industry. Dr. Wald is an active publisher of industry and company-specific research reports focused in the areas of cardiology and neurology. He has previous work experience in the medical technology industry, working at Guidant Corp. and Honeywell, Inc. At Guidant, Dr. Wald managed clinical programs as well as the development of the algorithms and software for two implantable defibrillators. He worked as a scientist and manager of image processing algorithm and robotics programs at Honeywell. Prior to joining A.G. Edwards, Dr. Wald was a Senior Vice President and Senior Analyst in medical technology at George K. Baum & Co. He has a Ph.D. from Brandeis University and an M.B.A from the University of St. Thomas. Dr. Wald also holds a patent on atrial fibrillation detection.

to-fore they really have not participated. They are also launching two new key product lines in the States: in contact lenses (specifically for the multi-focal segment for the aging baby boomer) as well as new silicon hydrogel technology. And then from a mid- to a larger-cap standpoint, there are companies like Alcon Inc. (NYSE: \*ACL \$55.11), clearly the 800-pound gorilla in ophthalmology, dominant share in cataract surgery, as well as the number two player in refractors. It is in the top three in ophthalmic pharmaceuticals, but at the forefront as you move forward now into the back of the eye. Those are the types of companies we think still have some multiple expansion potential at this level.

**GOMBRICH:** You know, obviously the analysts generally focus on what we refer to as smaller tranches of the large company. I would like to know what their assessment is of the capital market, both from a private as well as a public sector, for the smaller companies and companies that have yet to reach the level where a typical analyst is studying them.

**WALD:** I think you are right. It looks like we spend most of our time on the larger-cap companies, but I in particular have an interest in the smaller caps. I have noticed in terms of capital formation that it has been a pretty horrible three years, where I think if you are a small company or a privately-held company you have to go to extraordinary measures in order to raise capital, for the most part. There are always stories of how it comes easy, but I think from a capital raising perspective, it has been very difficult for companies to

go out and find resources, which has meant that they have had to be pretty innovative in their approaches. I think a lot more “strategic relationships with larger companies” have been formed. Or if not, a large number of the investments that have been made in the smaller companies have been by the larger companies, just sort of feeler investments to see what is going on, see what is happening. I would say in the last six months I have noticed a little bit of a change for the better. I think, in terms of the capital-raising environment, more private companies are looking toward going public. I think they see the interest in the market coming toward them. From talking to the institutional investors, it sounds as if they are also more intrigued by dipping back into that part of the space. So I think the climate is improving. I wouldn't say it is good, but I think it is improving.

**WSR:** Bill, any observations on the market environment in terms of financing?

**PLOVANIC:** Actually, I would concur with what Jan said. I would just like to point out that, of my coverage list, actually 13 out of my 17 names are below a billion [in capitalization] and 6 of 13 are below \$250 million. So we are more focused on the smaller names. But I would say over the last six months, the window is starting to open, and the smaller companies will have more opportunity to raise money. And the institutional investors are much more inclined to look at stocks that may not have earnings in the near term or even visibility, but are more potential-type names.

**WSR:** Sometimes in past years, med-tech has come to the market quite a bit.

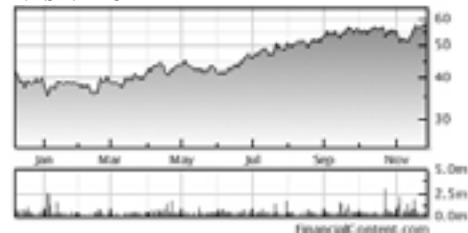
Are you hearing rumblings about people getting ready to come to market to raise capital?

**PLOVANIC:** Certainly eyebrows have been raised as we see some of the names coming through, and I do think there is a possibility that we are going to see a lot more going forward. You would have to talk to my banker, though, for what is really going on.

**WSR:** Any specific stocks to highlight while you have the floor?

**PLOVANIC:** The names that we talked about are the neurotechnology names, the Advanced Neuromodulation Systems Inc. (NASDAQ: \*ANSI \$41.00), and the Cyberonics Inc. (NASDAQ: \*CYBX \$27.35). These are the companies that I talked about: pacemaker-like technology. Using that for unmet clinical needs, and in the case of ANSI it is for chronic pain, and for Cyberonics it's depression. And what these companies do is they tend to look at the bottom-of-the-barrel patients, ones that have fallen through the cracks and have no other alternatives. Both of these companies are looking at other indica-

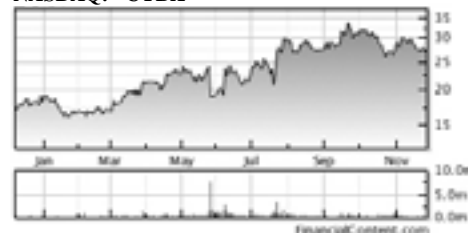
NYSE: \*ACL



NASDAQ: \*ANSI



NASDAQ: \*CYBX



**“Looking at the neurotechnology space, we think that they’ve run pretty well also, but long-term I think there’s a lot more upside to those names. So, we keep a “buy” on them. But again, I mean long-term focused. Near-term, these stocks are becoming fully valued.”**

tions. Cyberonics is probably the closest, getting ready to submit, actually, within the next couple of weeks to the FDA an application for approval on a depression indication. And then ANSI is looking to start studies in occipital headaches and angina as well.

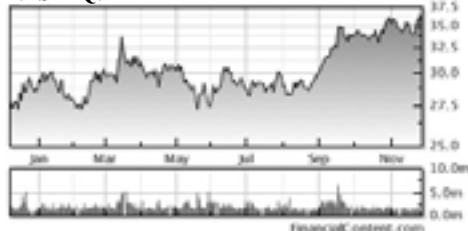
**WSR:** Jan, in spite of some of your caution, are there some stocks you would like to highlight positively at this point in the cycle?

**WALD:** I think I would agree with Bill on the names that he mentioned. I think those are both interesting companies and I think there is upside potential in both of them. On the large-cap side, my particular favorite at this point is Guidant. I should probably tell everybody that I have Guidant stock in a 401(k) because I used to work at Guidant. But I think there is some room for it to move higher as well, primarily because it is starting to get into the stent game once again, and I think both the physicians want to see that happen and industries want to see that happen. I think one of the things that is left in the larger caps is stories and I think Guidant still has a story to tell. I think as the story unfolds, people will become more interested in it and the stock will move higher.

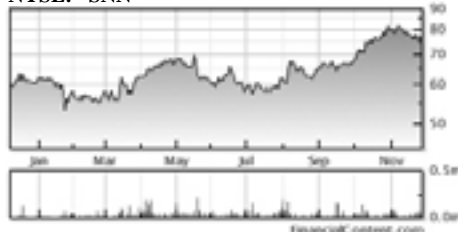
**WSR:** Back on the company side, Patrick, in terms of Pro-Dex, what are some of the key specific medical applications that you are working on that might have interesting milestones coming up?

**JOHNSON:** I think Jan’s depiction of market valuation is certainly an accurate description of the landscape that our equity growth strategy is built on. We have really reinvented the company in the last couple of years based upon strategic partnerships with the large-cap medical companies, primarily the orthopedic companies. We suppose that we have multiple relationships with Medtronic and multiple relationships with Biomet Inc. (NASDAQ:

NASDAQ: \*BMET



NYSE: \*SNN



\*BMET \$35.86) and are doing work for Smith & Nephew Plc (NYSE: \*SNN \$80.07) in particular, I think. While the evaluation may have matured in the ortho companies, we see a lot of movement inside the ortho companies wherein they try to get second lives out of existing implants with new indications. Smith & Nephew came to us a couple of years ago

#### Patrick L. Johnson

Patrick L. Johnson is the Chief Executive Officer and President of Pro-Dex Inc. In addition to this position assumed in September 2002, he joined the Company’s Micro Motors subsidiary as Vice President and General Manager in March 2000. Mr. Johnson has significant experience in dental manufacturing, having served as General Manager of Analytic Endodontics, Inc. (a division of Sybron Dental) from 1997 to 2000 and General Manager of Tycom Dental, Inc. from 1996 to 1997, both dental related product manufacturers. Mr. Johnson received B.A. degrees in Legal Studies and Philosophy from the University of California in Santa Cruz and a MBA degree from Pepperdine University.

with a minimally invasive indication for one of their Uni Knee implants. They needed a new drive and the patient system to be able to do that, and we were able to leverage our expertise in helping them create that drive system. They are now getting a new life out of an implant that they had out in the market for quite a while under the name Accuris. So we really see our long-term growth associated with the large caps, the ortho companies as well as the dental companies. Another exciting product that we recently released is a product that treats dental caries with the delivery of ozone gas, as opposed to the traditional drilling and filling of your teeth. There is probably no experience that I hate more than going to the dentist’s office. But we have come up with a minimally invasive device whereby instead of anesthetizing the patients, drilling out the dental decay to get to healthy tooth structure and then filling it, we are dealing with the decay on a microbiological level. The microorganisms that create the decay are killed, and the mouth is then left to heal itself. So, in cases of minor to moderate decay, we are actually seeing 90% plus complete regeneration of tooth structure after a treatment with this device. We are really excited about that. We are at the front end of the FDA process for approval in the United States, but the product is selling in Europe and the Middle East right now and we are both impressed with the clinical results as well as the continuing research on the product.

**WSR:** Brad, at Biowave, where are you in terms of key milestones with your most important projects right now?

**SIFF:** It’s been a very exciting year for us. We continued to collect a lot of important clinical data. We’ve got excellent double-blind randomized crossover data from Weill Medical College of Cornell University comparing Biowave against active control, TENS. And in that study,

**William J. Plovanic, CFA**

*William J. Plovanic is a principal and equity analyst covering medical technology. Bill joined First Albany in March 2001, after serving as a research analyst covering medical devices and products at PMG Capital. Prior to PMG, Bill was the director of research for the Capital Markets Division of LaSalle St. Securities, Inc. in Chicago, IL. He was responsible for management of the Research Department, in addition to coverage of the small-cap healthcare technology and biotechnology industries. Bill started his career as a diversified healthcare analyst with Madison Securities, Inc. in Chicago. Mr. Plovanic graduated from Bradley University, Peoria, Illinois, with a Bachelor of Science degree in Finance. He is a Chartered Financial Analyst (CFA) and is a member of both the Association for Investment Management and Research (AIMR) and the Financial Analysts of Philadelphia, Inc. (FAP).*

we obtained 80% reduction in pain post treatment and patients still had a 65% reduction in pain 24 hours post treatment. Whereas when they were treated with TENS, they had virtually no pain relief at 24 hours post treatment, hence providing little pain relief.

**WSR:** Just for those who don't understand, TENS refers to what?

**SIFF:** Transcutaneous electronic nerve stimulation. It is a typical electric-stim type of device.

**WSR:** Is that invasive or non-invasive?

**SIFF:** That is non-invasive. We also formed a relationship with a major Japanese partner that we are finalizing discussions with. As part of their due diligence, they wanted to run their own clinical study in Japan, and they ran it at a major university medical school on 94 patients, a third of them with low chronic back pain, a third with arthritic knees, and a third with painful shoulders. And they replicated the results that we obtained at Cornell: patients had approximately an 80% reduction in pain in all the various treatment areas, and that pain relief lasted for hours and finished at about a 65% reduction in pain in 24 hours. They were so impressed with the results that they immediately entered into negotiations with us regarding licensing our technology, marketing, and manufacturing devices using Biowave's technology in the Japanese market. Another major milestone is our core signal technology patent issued in June of this year. We've got four other pending patents now; one of which has had an official action. We are running a major clinical study with a professional

football team and getting excellent results on that clinical study. The team has used Biowave to treat sports-related injuries all through its mini camp and training camps. They've been using Biowave during the entire season, and use it today. So that's been very exciting for us.

**PLOVANIC:** Are they one of the two undefeated teams?

**SIFF:** No. One of the local area teams where we are located.

**“The opportunities in neurology and in the neuro space are so large that even though the companies keep approaching fair value, the opportunities in some sense outweigh evaluations, at least in our perspective, and that leads to us continuing our ‘buy’ recommendations.”**

**WSR:** Peter, with Molecular Diagnostics, where are you in terms of your key milestones?

**GOMBRICH:** In the product development side, the second generation of the assay for cervical screening came out. We completed about a 12,000-patient study around the world. When the company ran into financial difficulties following the tragedy of 9/11, it gave us an opportunity to unbundle some of the clinical file data and to take a look at how well we performed. And during that period of time, we made some determinations on how to make the assay even better than it was originally. The results of the clinical trials significantly show far better results on this than with a pap smear. For a high grade in cancer, we are at 99% positivity and our specificity is greater than 80%. The signif-

icant thing that is important about this is that not only is the data more compelling, but it is a much lower cost and could be done in underdeveloped parts of the world where you don't need the expertise of a cytotechnologist or a professional. The fully automated system can be done in essence at a point of service. Critical women were getting access, in fact, where subsequent treatment is virtually impossible. We see the market outside of the United States being early entry for us, and in fact, we have done clinical trials outside the United States as well as in the U.S. We have strategic discussions that are going along and that is where we are focused. We are focused not only on a distribution standpoint, the strategic partners standpoint as well. The latter is also helping us do manufacturing, kitting of the assays, and working with us in certain laboratories where we can actually sell the assay as a part of a kit for doing what they refer to as analyzing specific agents. It gives us

a little bit of revenue, and more importantly, it gets the test in the hands of laboratories so they can get comfortable with the efficacy of this test against the pap smear. One of the things that has set a new paradigm in regards to the critical aspects of the system is that we do not do anything that will destroy the cervical cells, such that you can use the assay on exactly the same sample. You can put a pap smear vein on top of it so that you can use the patient as her own control, and that has, we believe, made it a lot easier for adoption. People can do their own evaluation, a mini clinical trial, or a mini study within their laboratories or offices outside the United States. Our critical piece right now is not the focus on the development side. There are two pieces that we working very diligently with. One is completing our

**“From a capital raising perspective, it has been very difficult for companies to go out and find resources, which has meant that they have had to be pretty innovative in their approaches. I think a lot more ‘strategic relationships with larger companies’ have been formed.”**

current discussions with four companies, specifically in the area of strategic alliances. Our strategic deals deal with financial support, as well as distribution and manufacturing, and they are multinational in scope. The other, of course, is for us to get our balance sheet cleaned up and get additional capital into the company to enable us to get the submission to the FDA in the Q1 of 2004. At that time, we will be in a position to start to sell this product internationally in certain markets such as China. That is our focus and we have some very powerful scientific teams, with people onboard who've had experience in the molecular field. We are very excited about completing this process and getting the product to the marketplace.

**WSR:** *One thing I seem to be hearing from everybody certainly sounds like part-*

*nering is going to be very much in the forefront of a lot of these developments, certainly in the smaller companies.*

**PLOVANIC:** If I can say one thing, just to echo what Jan was saying: At least in the big-cap orthopedic space, these companies are performing nicely. They are generating a lot of cash, but they are going to need to keep that growth rate intact as we move into next year when currencies could turn against them and pricing could moderate a bit. These companies will need to either partner and maybe even make acquisitions to maintain their top and bottom line growth rates. We never recommend buying a small-cap company on the hopes of a takeout, however, we do believe that could help prop up valuations as we go through the end of this year and early next year.

**GOMBRICH:** Because that is the focus for our company, I just want to point out that we have seen in the last six months a dramatic change in that regard. Companies that had earlier discussions and nothing seemed to move ahead, all of a sudden, in the last few months come back, and there is a great deal of interest.

**WSR:** *Anything else to add to the investment discussion?*

**WALD:** I guess what I have learned is that there is a reason why one is going to focus on small caps, I think in terms of looking for opportunities there, rather than maybe the larger brethren. And in order to make a decision about what to do in small caps, I think one does have to understand what is happening in the large-cap names.

**SIFF:** I just wanted to comment on the partnering. I think that has been essential from my perspective toward our development and funding purposes. And we continue to look for partners in other markets, both in the U.S. and Europe as well. So, if any of the analysts have thoughts relative to that and want to speak afterward, I would be happy to do that.

**JOHNSON:** Just speaking to the partnerships. Particularly in the last year's heightening of corporate governance and regulatory compliance, I think it is very difficult for a small-cap company to be a publicly traded company. The cost of a public company is extraordinarily dilutive to earnings, and you have to work hard to cover those costs and then have something left over to re-invest in the company. And so, as a part of our strategic model, we are looking for strategic partners who have established sales and distribution in place. Then, we can focus on what we do well, which is developing and manufacturing products, and really draft off of their ability to take those products to market and deliver them. And that's really where we see our top line growth coming from. ■

#### **Bradford E. Siff, M. Engr., MBA**

*Mr. Siff serves as Biowave's Board Chairman, CEO and President, is the founder of the Company, and is responsible for its vision and day-to-day operations including raising and managing capital to fund the business, design of the professional and consumer pain management devices and disposables, developing and refining applications of the Biowave non-invasive electronic pain management system, designing protocols and managing clinical studies, and creating and implementing the marketing strategy for the company. Before founding Biowave, Mr. Siff joined CDI, a company that had a license to an advanced, patented, non-invasive dental electronic anesthesia system. Mr. Siff developed and managed the Company's initial test market and product introduction. He grew the company from 5 to 85 people and from \$0 to \$2 million in revenue. Mr. Siff developed the financial and business models and created and implemented the marketing strategy to sell dentists a non-invasive dental electronic anesthesia system that provides anesthesia without needles, numbness or chemicals. Mr. Siff managed the sales force, technical training and customer service organization and operations. He also initiated and managed U.S. clinical studies of the dental device. Mr. Siff also helped to dramatically improve the quality and performance of the device in conjunction with the Company's contract manufacturer, and performed FDA QSR audits to ensure proper record keeping in accordance with FDA Quality System regulations. Before joining CDI, Mr. Siff was Vice President, Mergers & Acquisitions for Daiwa Securities America, Inc. During his six and a half year tenure at Daiwa, he was responsible for new business generation and directing technology related mergers, acquisitions and strategic advisory transactions for Daiwa. Mr. Siff holds an MBA degree from the Samuel C. Johnson Graduate School of Management at Cornell University. He holds a Masters of Engineering and was awarded a teaching fellowship from Cornell University's Graduate School of Operations Research and Industrial Engineering (OR & IE), and he received a Bachelor of Science degree in Mechanical Engineering from Cornell.*

# 12.8 million dollar licensing deal committed to pain blocker device

**B** iowave Corporation is a medical device company that has developed a patented medical device that uses proprietary technology to send an electronic signal into deep tissue in the body blocking the transmission of pain. Clinical studies have shown that the Biowave device provides results similar to implantable neuromodulation devices with a minimally invasive procedure in a pain clinic setting, without the risk and at a fraction of the cost.



**Bradford E. Siff**  
Chairman, President  
and Chief Executive  
Officer

URL: [www.biowave.com](http://www.biowave.com)  
Phone: 203-855-8610



Bradford E. Siff, Chairman, President and Chief Executive Officer, spoke with *Wall Street Reporter Magazine* on October 10, 2003.

**WSR:** *Could you start first with an overview of the company?*

**SIFF:** Biowave has developed a proprietary pain management medical device that sends a pre-mixed high frequency signal into deep tissue in the body, and the body causes the creation of a low-frequency electric field in the deep tissue, which blocks the transmission of pain signals. A 20-minute treatment provides an 80% reduction in pain and what's most remarkable is that the pain relief lasts for up to 24 hours. We can treat any type of musculoskeletal pain — chronic, acute, or post-surgical in nature. We can treat the lower back, hip, ankle, elbow, knee, shoulder, and most locations on the body.

**WSR:** *What can you tell us about the market potential for the device?*

**SIFF:** The market is huge. If you talk with any pain physician at a pain clinic, they will tell you that this gap exists between non-invasive pain treatment modalities like prescription drugs and referring patients away to physical therapy, and very invasive pain treatment modalities like injection therapies, surgical procedures, and implanted neuromodulation devices. Prescription drugs have terrible side effects, are expensive, and all of the invasive procedures carry a lot of risk and are also expensive. As an example, for low back surgery, only one third of the cases get better; one third stay about the same and one-third get worse. For implanted neuromodulation devices, the cost is prohibitive, \$25,000 for the cost of the device and the surgery, and there is a significant annual maintenance cost as well. So, there is a need for a very efficacious treatment that is minimally or non-invasive, with no side effects, is of reasonable cost, and meets this gap that exists for treating pain, and Biowave is exactly designed to meet that gap. We are positioning Biowave as a first treatment foundation therapy that the pain physician can use first when treating a patient coming into a pain clinic.

**WSR:** *What can you tell us about the technology platform that is unique to the Biowave device?*

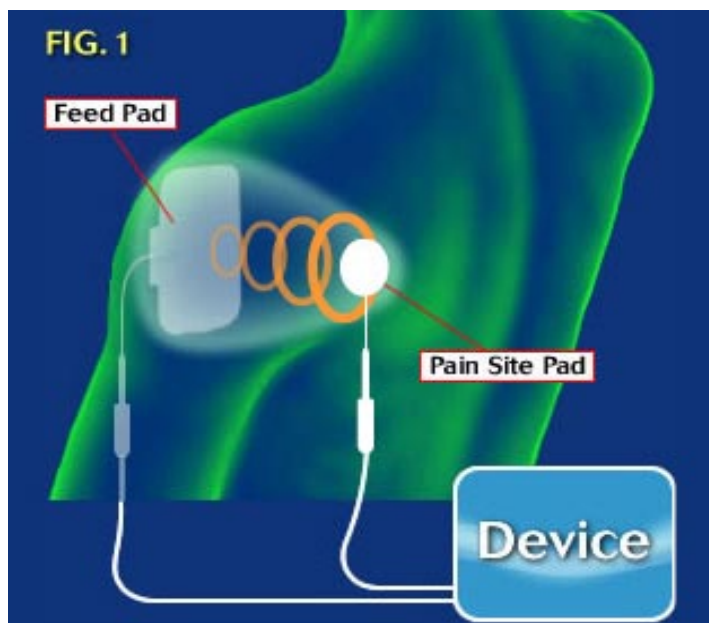
**SIFF:** There are two components of it. The first part is the signal technology and

its uniqueness comes from combining these signals to get them into deep tissue in the body. Conventional electrotherapy signals travel parallel or along the surface of the tissue and never get below the skin layer. Biowave signals travel perpendicular to the tissue between two opposing pads, one placed directly over the pain site, one opposite the pain site. We are able to create a low-frequency electric field in deep tissue encompassing the pain site and blocking the polarity change across the wall of pain fibers inhibiting the transmission of pain signals.

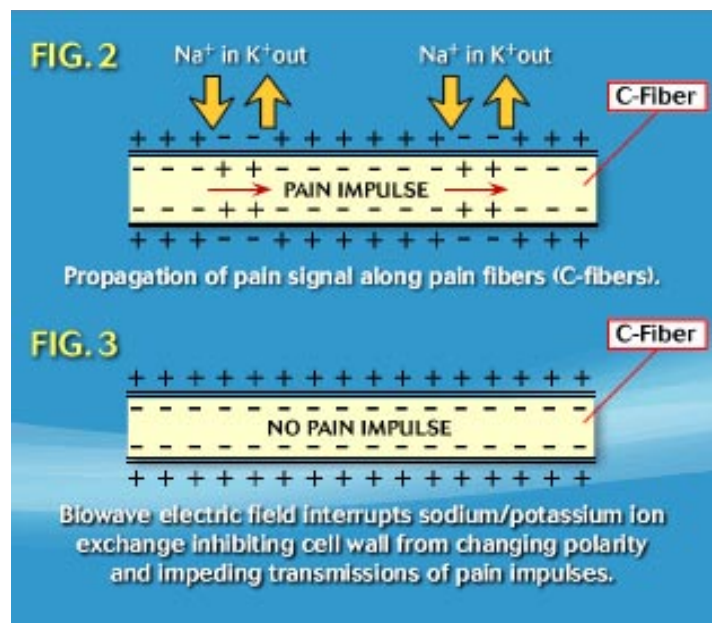
The other unique aspect of the technology for the pain clinic or the clinical product is the proprietary percutaneous electrode array, which is a minimally invasive electrode. It's a micro needle array that penetrates the outer two layers of skin. It's very comfortable. There are 3,600 micro

## SUMMARY

Privately held Biowave has created a minimally invasive device that blocks pain signals within the body, regardless of their source. The proprietary technology provides cost-effective relief for up to 24 hours. The company is currently seeking \$7 million to develop the product from prototype to the market by early 2005. The leading Japanese electrotherapy company has already committed to a \$12.8 million licensing deal; the company expects to derive \$160 million from the product through 2010. Other target applications of the technology include pain clinics and athletic training camps. In total the U.S. pain management market is estimated at \$100 billion, with \$1 billion of that on the pain clinic side.



The Feed Signals pass through the body to a second proprietary disposable pad at the treatment site called the Pain Site Pad.



A similar mechanism to local chemical anesthesia, except without any deleterious side effects.

needles in a two-inch diameter patch, which allow for a direct conductive pathway through the outer layers of skin. It's very comfortable; feels like fine sand paper — no irritation, bleeding or anything like that. It allows for a single-use disposable, it is a wonderful business model and there's a very high reimbursement component in the pain clinic market. There are other markets that we are also focused on that include rheumatology, sports medicine and orthopedics as well.

**WSR:** I understand that the company is also targeting both professional and consumer markets. Can you elaborate more on that?

**SIFF:** Typically what would happen is that once patients are at the place of last resort, where they have tried different therapies that haven't worked, they go to the pain clinic. The first choice foundation therapy would be for the pain physician to treat the patient with Biowave and perform four to 10 treatments, and if the patient is having success with those treatments (we have an 80% success rate empirically, by the way, from our clinical trials) then the physician would write a prescription for a home version of the device. So, the patients could continue to manage their pain in a home setting and

that would be a non-invasive version of the device using a proprietary non-invasive electrode designed to work with the home pain management system.

**WSR:** As far as it relates to the professional market, in hospitals and clinics, what can you tell us about the healthcare savings on that side?

**SIFF:** Our treatment is a much more cost-effective treatment than other alternatives. Drug therapies today cost anywhere from \$1,000 to \$3,000 annually,

or non-invasive version of our device.

**WSR:** How is the company progressing in its clinical trials with the FDA?

**SIFF:** We have excellent results. We ran two dosage studies, one at Weill Medical College of Cornell University which is New York Presbyterian Hospital, followed with a double-blinded randomized crossover study comparing Biowave against an active control, a transcutaneous electronic nerve stimulation (TENS) device, which is a traditional electric stim

**“There is a need for a very efficacious treatment that is minimally or non-invasive, with no side effects, is of reasonable cost, and meets this gap that exists for treating pain, and Biowave is exactly designed to meet that gap.”**

and at the other end of the spectrum, it's a similar cost for providing injection therapies. An implanted neuromodulation device, which would really be your treatment of last resort, costs approximately \$25,000. That's the cost of the device, plus surgery, and the clinical results for that type of device are reported as 60% of the patients get a 50% to 75% reduction in pain. Our clinical results are as good or better than that with a minimally invasive

device. Biowave provided an 80% reduction in pain following the 20-minute treatment, whereas TENS only provided about a 60% reduction in pain. But at 24 hours following the treatment, the Biowave patients still had a 65% reduction in pain, whereas the patients with the TENS treatments had close to zero pain relief.

So, the difference is huge and that's what has really fascinated the pain physicians the most.

**“It allows for a single-use disposable, it is a wonderful business model and there’s a very high reimbursement component in the pain clinic market. There are other markets that we are also focused on that include rheumatology, sports medicine and orthopedics as well.”**

**WSR:** *What is the next step in terms of capital formation moving forward with your strategy and mission?*

**SIFF:** We have raised \$2.5 million to date for the company, and are in the process of raising a \$7-million institutional round. We have about \$2 million soft circled already from several Boston-based venture capital firms and we are in discussions with a couple of other firms interested in acting as the lead in the deal.

**WSR:** *What can you tell us about the management team that you’ve assembled?*

**SIFF:** Aside from myself, I’ve brought on board as our chief operating officer, Pat Maley, who was vice president of sales and marketing at Boston Scientific and he was also VP, sales and marketing at Zoll

and an M.D. That’s how I got introduced to John Carter, our director of R&D. John took my concepts and invented the technology that we have today. The three of us are really the core team. We have outsourced everything else as we need to build the company to this point, and probably the next key person we bring on board is a top-notch clinical/regulatory person.

**WSR:** *It sounds as though the company has made significant strides in the course of the past year. What can you tell us of those highlights that you would note to our audience?*

**SIFF:** One of the key things was our first patent issued in June of this year. It’s a core signal technology patent. We also have four other patents pending. On two of

football team and have been working with them since their June mini-camp and into the July/August training camps, and they asked to continue the clinical study through the entire football season. We’ve been getting excellent results and that could be a very promising market for us as well.

**WSR:** *What markers should we keep on our radar screens to judge the company’s relative progress in this area?*

**SIFF:** Well, the next key thing will be to finish and complete the commercialization of the product, the industrial design, mechanical engineering, and software. We already have the circuit fixed and completed. Then the next step is to build beta-prototypes, file a 510 (k) application with the FDA, run one more major clinical study with our Percutaneous Electrode Arrays, obtain an additional 510(k) approval, and launch in the Pain Clinic marketplace in early 2005.

**WSR:** *In closing summary, point out the value proposition offered by Biowave Corporation in the near term and beyond.*

**SIFF:** We have a unique proprietary technology and we’re operating in a very large market. One hundred billion dollars is spent annually in pain management in the U.S. alone and the pain clinic market in which we’re initially focused is a \$1 billion market. The regulatory pathway is fast, reimbursement is attractive, and there is a compelling economic reason for the pain physician to use the Biowave technology. We have a very reasonable valuation. We have eliminated most of the risk out of the entire business model. The technology is proven; the clinical studies have validated the Biowave technology. We have an excellent management team in place. And so we really have all the pieces of the puzzle in place to make this a very successful company. ■

**“We’ve signed a letter of intent with a major Japanese strategic partner, a \$4-billion company that is the leader in the electrotherapy market in Japan, where they own 70% of the market share [and are] projecting \$160 million in revenue over the first five years of the deal.”**

Medical and at Alcon before that. Pat has also been involved in a number of start-ups. So, he brings to the equation a very strong operating and marketing background that, combined with my very strong technical and financial background, is very complementary and really makes us a great team. Our chief scientist is a brilliant research scientist out of Cornell. When I originally started the company, I had a concept for this technology and I have a background at Cornell Engineering æ an undergrad, masters, and an MBA. So, I went back to the engineering school and asked the Dean if he knew of a scientist with a Ph.D. in electrical engineering

them we’ve just recently had office actions so it now looks like we will have another two patents issued within the next six months. We’ve signed a letter of intent with a major Japanese strategic partner, a \$4-billion company that is the leader in the electrotherapy market in Japan, where they own 70% of the market share. They sell one million electrotherapy devices per year today. We negotiated a \$12.8 million deal; \$1.8 million of that in license fees upfront tied to milestones. The Japanese partner is projecting \$160 million in revenue over the first five years of the deal. We also are running a major sports medicine clinical study with a professional

# Biowave Corporation

Private Equity

## Corporate Headquarters

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## Corporate Officers

**Bradford E. Siff**  
*Chairman, CEO & President*

**Patrick Maley**  
*Chief Operating Officer*

**John Neil Carter, Ph.D.**  
*Director of Research & Development*

**Tom Muller, Ph.D.**  
*VP Regulatory & Clinical Affairs*

## Corporate Profile

Biowave is an early stage minimally invasive pain therapy medical device company initially targeting the \$1B+ Pain Clinic market. Biowave's patented signal technology is similar to that of implanted neuromodulation devices, however, the Biowave procedure can be performed in the Pain MD's office, is much less invasive, has far less risk and is a fraction of the cost. The patent pending single-use disposable is a 2x2 inch percutaneous electrode array (PEA) with 3600 "comfortable" micro-needles that deliver a "pain blocking" electric field through the body into deep tissue.

Multiple clinical studies at Weill Medical College/Cornell University/NY Presbyterian Hospital (including double blinded, controlled randomized studies) have shown that a 20-minute treatment provides patients average an 80% reduction in pain at 1-hour post treatment and patients maintain more than a 60% reduction in pain at 24 hours post treatment, unlike any competitive technology. Patients also obtained a significant increase in range of motion as a result of the Biowave treatment in all studies.

The patient-controlled Biowave pain management device can be used to treat joint or muscular related chronic, acute or post-surgical pain in the low back, shoulder, neck, hip, knee, elbow, face, legs, arms, wrist, hands, ankles and feet, without harmful side effects. Use of the Biowave device reduces or eliminates the need for morphine, narcotics and other painkillers, providing a much better quality of life.

## Technology:

The patented Biowave system introduces two pre-mixed high frequency electronic wave forms ("Feed Signals") into the body minimally invasively or non-invasively through a proprietary percutaneous electrode array (PEA) placed on the skin opposite the pain site called the Feed Pad. The Feed Signals pass through the body to a second PEA at the treatment site called the Pain Site Pad.

Polarized structures and in particular, nerve fiber membranes, that lie along the line vector in the body between the opposing pads act like nonlinear devices, causing the Feed Signals to mix, resulting in the formation of an electric field. The electric field contains a specific low frequency component that interrupts the transmission of pain by preventing the polarity change of nerve cells along the membranes of pain fibers (C-fibers) – a similar mechanism to local chemical anesthesia, except without any deleterious side effects.

The use of different sized pads forces the formation of a high density, low frequency electric field in the volume of tissue surrounding and beneath the Pain Site Pad. The size of the volume of tissue affected can be changed and is dependent upon electrode placement, geometry and materials, as well as the amplitude of the Feed Signals. The sensation felt by the patient is a comfortable pressure and tingling sensation without muscle twitching or side effects that are common to prior electrotherapy devices.

## Clinical Studies:

The Company has sponsored several clinical studies for marketing purposes that are run under local Investigational Review Board ("IRB") approvals. Additionally, the Company's strategic partners have also run clinical studies to evaluate Biowave's safety and efficacy as part of their own due diligence.

### Clinical Study #1:

Dosage Study to Determine (1) Optimal Device and Disposable Parameters and (2) Preliminary Efficacy for the Treatment of Chronic Low Back Pain.

Weill Medical College of Cornell University/New York  
**Presbyterian Hospital**  
New York, NY

### Clinical Study #2:

Dosage Study to Determine (1) Optimal Parameters for the Disposables and (2) Preliminary Efficacy for Treating Pain in the Neck, Face, Shoulder, Elbow, Wrist, Hip, Knee, and Ankle.

**Coren Clinic**  
Norwalk, CT

### Clinical Study #3:

Blinded, Randomized, Controlled, Crossover Study Comparing Biowave vs. TENS (as an Active Control) for the Treatment of Chronic Low Back Pain.

Weill Medical College of Cornell University/New York  
**Presbyterian Hospital**  
New York, NY