ORTHOLOGIC CORP
Form DEFA14A
October 28, 2003

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**SCHEDULE 14A**

**INFORMATION REQUIRED IN PROXY STATEMENT**
**SCHEDULE 14A INFORMATION**

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**ORTHOLOGIC CORP.**

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**OrthoLogic Corp.**

**Presentation at Rodman & Renshaw Techvest Healthcare Conference**

**October 21, 2003**

**Mr. Jaikaria**: Good morning everyone. We re going to kick off this morning s session here. My name is Navdeep Jaikaria. I am the senior analyst with Rodman & Renshaw, and I will be the moderator for this session. We are going to kick of this session with OrthoLogic Corp, ticker OLGC. OrthoLogic is a specialty orthopedic company. They have products which address fracture healing and spinal repair markets, and they have their lead product is in Phase III trials, and they also have some other products in earlier clinical development. So without further ado, I d like to welcome Tom Trotter, President and CEO, who will come and tell us about OrthoLogic. Tom.

**Mr. Trotter:** Thank you very much, and good morning. I appreciate you coming to visit with us today. OrthoLogic is a medical device company. Currently, we are located in Tempe, Arizona, and we are in the orthopedic business. We are traded on the NASDAQ OLGC. Joining me this morning for our presentation is Dr. James Ryaby. Dr. Ryaby is our Chief Technology Officer. I need to read a short forward-looking statement here, if you can bear with me for a moment. The following presentation contains forward-looking statements that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements, which include estimates of future market size revenues and manufacturing costs statements about the expected timing of clinical testing, and the timing accessibility of FDA fillings, the efficacy and marketability of potential products involve risks and uncertainties that could cause actual results to differ materially from predicted results.

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These risks include: our possible need to raise additional capital to fully develop the Chrysalin program if we do not successfully complete the sale of our bone stimulation business to dj Orthopedics, in accordance with the proposed terms; unfavorable outcomes in our pre-clinical and clinical testing, development of others, competing technologies and therapeutics that may have greater efficacy or lower costs, delays in obtaining or inability to obtain FDA or other necessary regulatory approvals of our products; inability to successfully and cost effectively develop or out-source, manufacturing or marketing any product we re able to bring to market; change in the FDA, or other regulations that affect our ability to obtain regulatory approval on other products, increasing our manufacturing costs or limit our ability to market our products; and other factors discussed in Form-10K, fiscal year ended December 31st, 2002, and other documents we filed with the Securities and Exchange Commission. Thank you for bearing with me.

OrthoLogic today, is a medical device company, which also has a very exciting drug development program under way. We are, as I said, in the orthopedic business, and we operate in a segment of that business which is the bone growth stimulation market. Our current revenues for 2003 are projected to be 46 to 47 million. That would be a 20% year-over-year top-line growth rate. We have produced 10 consecutive quarters of increasing sales profitability and positive cash flow from operations. Currently, today, we have no long-term debt and approximately 40 million in cash on our balance sheet. Our current products today are the OL1000, a bone growth stimulator to treat non-union fractures. These are fractures of the long bones in the body. And SpinaLogic, which is a spinal stimulator used as an adjunct to spinal fusion surgery. Over the last five years, we ve been investing and working hard on our drug development program.

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It is a product called Chrysalin, which we re very excited about. It is an entry, potential entry, in the orthobiologic segment of Orthopedics, which many analysts believe is the future of orthopedic medicine. This is just the slide showing the 2 bone growth stimulator products, 1 for fracture repair, and the 1 for spinal fusion. This is a picture of the Chrysalin synthetic peptide, which is the cornerstone of our orthobiologic product platform. That platform is envisioned to have out of the Chrysalin program at least five products, perhaps more, and of those, we have 3 products currently well into development. One is in a Phase III human clinical trial, the second in a Phase I/Phase II human clinical trial, and a third that is completing pre-clinical work, and we hope to have a human clinical trial next year. And in just a moment, Dr. Ryaby will take you through those programs.

About ten days ago we announced a significant shift in our strategic plan for OrthoLogic. We had made the determination after our efforts in the Chrysalin drug development program to move exclusively in that direction for our future, and we announced the sale of our device business for $93 million in cash, plus certain assumed liabilities to an orthopedic company in Southern California, dj Orthopedics. The sale is subject to normal government approvals, fairly standard closing conditions and subject to shareholder approval by the OrthoLogic shareholders. We do anticipate that that will take place, and will conclude before the end of this year. Once that happens, OrthoLogic will then emerge as a pure play drug development company, focused in orthobiologics to my knowledge, one of the few publicly traded companies that is a pure play in orthobiologic development.

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Our goal is to commercialize a series of Chrysalin based products, for various orthopedic indications, and we are well along in that process. We re also continuing our discussions which we ve had with large orthopedic companies, as well as large pharmaceutical companies, about potential partnerships in the development of these products, and those discussions are continuing. We also would end up with enough cash, we believe, post-closing of this transaction to look at other orthobiologic technologies that might be compatible with our Chrysalin product platform. Assuming the close takes place as planned, we would immerge with about $120 million in cash, no long term debt on our balance sheet. At this point, I m going to ask Dr. Ryaby to come up, and take you through the Chrysalin story. I ll come back in a moment with a few following comments. Jim?

**Dr. Ryaby:** Good morning everyone. Thank you Tom. What I d like to do in the next 10 minutes or so is really just give you an update on where we are in the Chrysalin development program. Chrysalin is actually a 23 amino acid synthetic peptide that represents the receptor binding domain of thrombin. And just so everyone can understand the biological basis of this, what we re really talking about is, every time there is an injury such as a fracture, and you have a fibrin platform, thrombin gets sequestered in the fibrin clot, and then as it is proteolytically degraded, thrombin and fragments of the thrombin molecule are released, in a sequential fashion, and this acts as an early regulator of the overall fracture healing or wound healing response. And so what the group at Chrysalis Biotechnolgy did was actually to identify the receptor binding domain of thrombin, which is not proteolytically active, and can, in fact be used to accelerate the wound repair process, and we have actually licensed this technology for all orthopedic indications worldwide.

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What you re going to hear on Thursday from Chrysalis biotechnology, is their work in dermal wound repair as well as cardiovascular applications of the peptide, we have focused primarily on all the orthopedic indications.

So in terms of orthopedic preclinical studies, I d like to just spend a minute talking to you about this. We re going to talk about some fracture repair data, segmental defect repair data, and cartilage repair data. We ve use Tom Einhorn s closed femoral fracture model in many of these fracture repair studies, and what we found was actually with a single percutenaous injection of the peptide into the fracture site, compared to a saline injection to the fracture site, we could accelerate this is the mechanical strength of that healing fracture callus at earlier time points we could almost double the mechanical strength of the healing fracture callus, and then basically reach convergence out at eight weeks when that fracture is more fully healed. Histologically, at three weeks for example, what you see is, as other people have published, is if you look at that periosteal fracture callus, you always see four islands of cartilage remaining in the control here shown with saffron and o-staining, and what you see with Chrysalin is basically almost a complete replacement of that cartilage, with woven bone.

So again, this is really shifting that healing curve and accelerating the healing process. Overall, what we ve seen in about six animal studies of 1500 animals, was a 35% acceleration of healing, which essentially means that the four-week peptide treated mechanically is a strong as a six week control.

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We ve also looked at the peptide incorporated into the PLGA porous microspheres, and we ve looked at this both in a segmental defect model which represents a human non-union situation, as well as in cartilage defect studies. So if we look at this in this rapid ulnar segmental defect, so this is where you take a 1.5 centimeter segment of bone, out of the ulna of the rabbit, you can see that if you just fill this with PLGA microspheres, there s absolutely no regeneration of bone. If you formulate this in PLGA microspheres that give you a very slow release over thirty days, there s no effect. But if you use the shorter releasing microspheres, where basically we re getting 75% of the peptide released in the first 3 days, we actually see a very nice bone regenerate.

As I show you here, here s a high-resolution faxatron just showing you the regenerated bone, but most importantly, we do with a group at Lawrence Livermore National Labs in UCFF using the synchrotron source at Stanford. And if you look at this 3-D reconstruction of this regenerated bone, you can see really a complete regeneration of that segmental defect, as well as a restoration of the marrow cavity in these slices through the 3-D construct.

So, we believe that certainly in segmental defect repair, this controlled release formulation may provide some good human clinical applications. We ve also looked in articular cartilage repair, with this same formulation, where we basically make a 4mm critical sized defect in the rabbit, and you can see at 4 weeks for example in the controls, you still see some hematoma or granulomatous tissue present here, in the defect site.

What we ve seen with the peptide, both at a lower dose and a higher dose, is certainly some regeneration of the articular cartilage. Again, this is a widely used model, what you see in the

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empty defect is a complete restoration of the subchondral bone, but a thinning of that articular cartilage layer.

What we ve seen is PLGA is not very compatible with repair in this model, at least not these microspheres, you still see the defect. But what we see both with low and high dose is really a nice reconstitution of the subchondral bone, as well as some good evidence of cartilage repair. If you score this histologically, we re talking about a 75% repair, according to the O Driscoll scale. So hopefully, you have a flavor of some of the preclinical studies that we ve done, that certainly show the effects of the peptide. In terms of the regulatory pathway, this peptide is regulated as a drug by the FDA, so this means we are going through the IND/NDA process.

What I d like to do now is tell you about the results of our first clinical trial in orthopedics, which was basically a double-blind, randomized placebo-controlled Phase I/II trial, to look at the effect of an injection of this peptide, in distal radius fractures. In this study we had 90 patients in seven centers; patients were randomized to either one of two doses of Chrysalin, 10 or 100 micrograms, or placebo saline, and again this is a single percutaneous injection, into the fracture site, at the time of final reduction.

When we look at the safety results, of course this is a Phase I/II study, so it is critical to emphasize the safety results. We had no reportable serious adverse events in this trial, and there were no significant differences in adverse event rates amongst the treatment groups. This was also observed by Chrysalis Biotechnology in their Phase I/II diabetic ulcer study. In terms of an efficacy evaluation in this trial, we did both radiographic clinical evaluation, functional evaluation,

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as well as outcome assessment. And really our most significant finding was that the low dose Chrysalin treatment group, which is the 10 microgram treatment group, had a significantly statistically significant reduction in time to cortical bridging, compared to both the placebo, as well as the high-dosage Chrysalin group.

So what we gleaned from this study was certainly a demonstration of safety in these 90 patients, as well as preliminary efficacy. Most importantly, we were able to take this data, and power a Phase III efficacy trial, a pivotal study that s underway right now. We ve presented these results at national meetings. So now we have a current Phase III fracture trial underway. Again, it s displaced and/or unstable distal radias fractures. This trial is being performed in 25 to 30 centers in the U.S.; approximately 500 patients.

We have about 2/3 of the centers now actively enrolling patients. Again, this is a prospective randomized double-blind placebo-controlled IND clinical trial. The primary efficacy end point is actually going to be time to immobilization removal.

As many of you know, this is required to show clinical benefit, as required by the FDA for a new drug, but we certainly, for secondary efficacy parameters, will focus also on clinical, functional and radiographic parameters. We also have underway a Phase I/II spine fusion study. Really the point of this study is to assess whether Chrysalin mixed with allograft is actually as effective as autograph in spine fusion surgery. So that s the overall study design. If we look at the overall product pipeline, as I have told you, we ve done a lot of preclinical work in fracture repair. These preclinical studies really provided the scientific foundation to move into our first Phase I/II clinical

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trial in distal radius fractures, and as I said, we re now in a Phase III evaluation. In spine fusion, we ve done studies which basically now have led us to the Phase I/Phase II human clinical trial in cartilage repair, we believe we have a preclinical package now, which will support us moving forward in the first half of 2004, into a Phase I study, looking at that sustained release formulation for our articular cartilage repair in humans, and then we re in the preclinical planning stages for ligament and tendon repair.

So I think scientifically we have cost-effective synthetic peptide, with a well understood method of action. I didn t really get into talking to you about the receptor binding characteristics, or those studies, but I think you ll hear about them Thursday in the Chrysalis talk. It s effective in many orthopedic animals. We have a very good safety profile in humans, very excellent safety profile in animals, and very promising early human clinical data, and we believe is a very promising product platform. I d like to turn the podium back over to Tom.

**Mr. Trotter**: Thank you Jim. Just to summarize then for your here, we are initially looking at 3 of the most promising markets in orthopedics today. Fracture repair, which there are 7 million fractures generally speaking in the United States every year; perhaps 25 million fractures worldwide, as a potential opportunity, and spinal fusion worldwide, approximately 600,000 spinal fusion procedures, and then a large market opportunity in cartilage, ligament and tendon repair, something north of 3 million potential patients. So total platform potential, perhaps as many as 10 million patients worldwide.

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You put these into dollar market opportunities, we see the potential of these three markets alone, in excess of $3 billion, and we think again because Chrysalin is a synthetic peptide, and it is a very inexpensive to manufacture, has a lot of advantages in terms of packaging and shelf life, that we will find this product to be very competitive, if we re successful reaching the market.

Just to summarize for you the investment summary then. We have a successful medical device company that is transitioning to a pure play biotech, that is assuming a successful closing of the announced transaction with dj Orthopedics. We are active in the fastest-growing segments of the biggest medical device market in the world, which is the $13 billion orthopedic business. We have some very promising results, both in preclinical and in human clinical trials, with our Chrysalin product platform, and post closing of the transaction, anticipate having about $120 million in cash to fund our development efforts. Thank you very much for your time this morning. I would leave you with the thought that we believe that Chrysalin certainly has the potential to change the practice of medicine in orthopedics. Thank you.