

ORTHOLOGIC CORP  
Form DEFA14A  
October 10, 2003

**SCHEDULE 14A**

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**ORTHOLOGIC CORP.**

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**Orthologic Corporation  
Transaction Conference Call  
October 9th, 2003**

**Operator:**

Good morning ladies and gentlemen, and welcome to the OrthoLogic conference call. At this time all participants have been placed on a listen-only mode, and the floor will be open for questions following the presentation. I would now like to turn the floor over to Larry Delaney of the Berlin Group. Sir, the floor is yours.

**Larry Delaney:**

Thank you and good morning. Thanks for joining us to discuss this morning's pending transaction with the management of OrthoLogic Corporation. OrthoLogic management will provide an overview of comments, and then we'll open up the call to your questions.

But first, this call 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 involve risks and uncertainties that could cause actual results to differ materially. Factors that could cause or contribute to such differences can be found in the statement accompanying this morning's press release as well as the company's annual report on Form 10-K for the fiscal year ended December 31st, 2002 and other documents filed by the company with the Securities and Exchange Commission.

In addition, OrthoLogic will file a proxy statement, and other documents with the SEC regarding the proposed sale, which is the subject of this webcast conference call. OrthoLogic stockholders are encouraged to read the proxy statement when it becomes available because it will contain important information. A definitive proxy statement will be sent to stockholders of OrthoLogic, seeking their approval of the transaction. Investors and security holders may obtain a copy of the proxy statement, when it is available, and any other relevant documents filed by OrthoLogic with the SEC for free at the SEC's website at [www.sec.gov](http://www.sec.gov), and at the Investor page of OrthoLogic's website, [www.OrthoLogic.com](http://www.OrthoLogic.com). Copies of the proxy statement and other documents filed by OrthoLogic with the SEC may also be obtained free of cost by the directing your request to Barbara Dunford at OrthoLogic Corporation, 1275 West Washington Street, Phoenix, Arizona, 85281, telephone number 602-286-5520.

OrthoLogic and its directors, executive officers, and certain of its employees may be deemed to be participants in the solicitation of proxies of OrthoLogic stock holders in connection with the proposed transaction. Such individuals may have interest in the transaction, including as a result of holding options or shares of OrthoLogic common stock. A detailed list of the names, affiliations, and interests of the participants in the solicitation will be contained in the proxy statement that will be filed with the SEC.

With that, I'll turn the call over to Tom Trotter, OrthoLogic's President and CEO.

**Tom Trotter:**

Thank you Larry. Good morning, and thank you all for joining us to discuss the transaction we announced earlier today. With me is Sherry Sturman, Senior Vice President and Chief Financial Officer. Dr. Jim Ryaby, our Senior Vice President and Chief Technology Officer, had a previous speaking engagement for this morning, and will not be joining us for this call. However, he will be joining us for our regularly scheduled third quarter conference call, which will take place on Wednesday, November 5th. I will make introductory comments, and then we will open the call up to your questions.

First, to review this morning's headline, we have signed a definitive agreement to sell OrthoLogic's bone growth stimulation business to DJ Orthopedics for 93 million dollars in cash. The agreement also calls for DJ Orthopedics to assume certain liabilities related to the bone growth stimulation business. The transaction is subject to normal government approvals, customary closing conditions, as well as the approval of OrthoLogic shareholders. We anticipate that this transaction will be completed before the end of this year.

Once the transaction is completed, OrthoLogic will emerge as a pure-play drug development company focused in orthobiologics, an area where we see tremendous potential. Our efforts will focus on the potential commercialization of a series of Chrysalin-based products, which currently make up the Chrysalin product platform. Chrysalin product platform includes potential products currently in development for fracture

repair, spinal fusion, and cartilage defect repair. In addition, we anticipate potential future applications in both tendon and ligament repair.

At the outset of today's call, I want to clearly state that our purpose this morning is to briefly outline the decision-making process that led to this transaction. Second, to share with you why we believe orthobiologics will be a key growth driver in the 13 billion dollar worldwide orthopedics business. Finally, to explain why we believe Chrysalin is among the most promising early candidates to exploit the new opportunities in orthobiologics.

The purpose of the call this morning is not to provide updated financial guidance or to provide an update on the status of the Chrysalin product platform. As I indicated on our last quarterly conference call in July, we intend to provide this information on our next regular quarterly conference call on Wednesday, November 5th. At that time, we will review our third quarter financial and operating results, provide an update on the Chrysalin product platform, and give updated financial guidance for the balance of 2003 as well as 2004.

To begin with, I think it's important to reiterate OrthoLogic's stated strategic mission. Our long-term goal is to become a worldwide leader in the orthopedic market for fracture healing, spinal repair, and orthopedic soft tissue repair. In order to achieve that goal, since 1998, OrthoLogic has invested significant resources in the development of the Chrysalin product platform. We have done this because 1) we believe that orthobiologics will be a key driver of growth and profitability in the 13 billion dollar worldwide orthopedic industry going forward; and 2) we believe the therapeutics utilizing the Chrysalin synthetic peptides represent OrthoLogic's most promising means to achieve our long-term strategic goal.

In the early 1990's, several healthcare and medical specialty companies began evaluating a new class of orthopedic products called orthobiologics. This new class of products combines innovations in biotechnology with material sciences and tissue biology to utilize the body's natural capacity to regenerate and repair muscle-skeletal tissue. Although they make up just a fraction of the total worldwide orthopedic market today, many analysts view orthobiologics as a potential key driver of industry growth and profitability going forward. Today, many major orthopedic companies and several major pharmaceutical companies have active research and development efforts underway to bring to market orthobiologic products by one or more orthopedic indications.

In 1997 as part of a long-range strategic planning process, OrthoLogic began investing promising technologies in the orthobiologics arena. Our search led us to a development stage biotechnology company based in Galveston, Texas, called Chrysalis Biotechnology Inc. Chrysalis had developed and patented a unique small synthetic peptide, known as TP508, or Chrysalin, which had shown great promise in accelerating the healing process for both soft tissue and bone in pre-clinical animal studies. In early 1998, we made an initial equity investment in Chrysalis Biotechnology, and by July 2001, we had secured the license rights for Chrysalin to include all options for orthopedic indications worldwide.

As many of you know, Chrysalin is a synthetically manufactured 23-amino acid peptide that represents a portion of the naturally occurring human thrombin molecule. Thrombin is responsible for initiating some of the cellular events involved in tissue repair. Chrysalin mimics thrombin by interacting with specific thrombin receptors on cells involved in tissue repair without affecting the blood clotting activity of the naturally occurring thrombin. Chrysalin stimulates the body's own natural healing process, potentially resulting in accelerated tissue and bone repair.

We believe that as of this date, Chrysalin is the only therapeutic of its kind in U.S. human clinical trials. And because it is a small peptide, we believe it has numerous advantages over competing large molecules on the market and in development. The most important of these advantages include the following. To date, Chrysalin has shown an excellent safety profile, having been evaluated in more than 4,000 animals in pre-clinical studies over many years. In addition, in two completed human clinical trials, one conducted by Chrysalis BioTechnology for a diabetic ulcer indication, and the other by OrthoLogic for an acceleration of fracture repair indication, there were no reportable adverse effects related to the Chrysalin peptide.

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Chrysalin has shown evidence of acceleration of fracture healing in a combined Phase1/2 human clinical trial. Chrysalin can be manufactured at significantly less cost than large molecule products, which are created using recombinant DNA technology. Finally, Chrysalin is a very stable molecule, and offers numerous potential advantages in packaging and shelf life.

According to analyst estimates, the potential markets of OrthoLogic's Chrysalin product platform represent a combined opportunity of more than one billion dollars. Today, the Chrysalin product platform includes potential products in human clinical trials for acceleration of fracture repair, spinal fusion, as well as a third potential product in late stage free clinical development for cartilage defect repair. We also intend to develop Chrysalin-based products for tendon and ligament repair.

Over the last two years, we have pursued a dual strategy of building our bone growth stimulation business while at the same time investing significant resources in the Chrysalin product platform. During this time, we have continued to operate as essentially two businesses. One a device business based on bone growth stimulation, and the other a drug development business based on the Chrysalin technology. We have clearly achieved considerable success following this strategy as evidenced by ten consecutive quarters of double-digit sales growth, profitability as well as positive cash flow from operations. However, as a consequence of following this dual strategy, it has also been necessary to invest virtually all of the profits generated by the bone stim business in the drug development program. While we were able to effectively manage this challenging situation last year, and thus far in 2003, it would not be possible to continue this approach beyond the end of this year without putting OrthoLogic in a sizeable net loss position for the next several years. A small device company simply cannot afford to spend 20 percent of sales on research and development for a sustained period of time.

In addition to the ongoing operating and financial challenges, it has become increasingly difficult to present a clear picture of the potential we see in orthobiologics to both our existing shareholders and the investment community at large. We believe that, going forward, as a pure play in orthobiologic drug development we will provide the market with clearer and more favorable valuation metrics for our stock.

Over the last two years, OrthoLogic's board of directors has been carefully evaluating this situation, and reviewing strategic options available to the company to increase stockholder value. We have publicly discussed various strategic options in both past earnings conference calls as well as public disclosure forums, such as webcasted investor conferences. Among the various options considered, the three most attractive were, one, to continue to fund the R&D requirements of Chrysalin program from the existing device business cash flow. Our board of directors determined that this strategy would be viable in 2003. However, beginning in 2004 and beyond, this option was likely not to work without using cash on our balance sheet and resulting annual losses in net income. In addition, over the next five years, it would be very likely that the company would need to secure significant additional outside funding. Second option, to continue to fund R&D requirements of the Chrysalin program from the existing device business cash flow as well as secure a strategic partner to share the cost of the Chrysalin program in exchange for certain rights. This alternative would likely have generated sufficient funds to cover the development costs of the Chrysalin product platform over the next five years. In addition, it would likely have offered additional validation of the technology. However, in the discussions we have had to date with potential strategic partners, including major companies in both the orthopedic and pharmaceutical business, it was unclear whether a partnership arrangement would be truly advantageous to us at this time. Thus far, the discussions indicate that the price we would need to pay today in terms of the lost future marketing rights, as well as overall program control, would have been very high compared to the potential long term value we believe that eventually would be generated by the Chrysalin product platform.

Option three, to sell the bone growth stimulation business, and become a pure-play orthobiologics company, focused on commercializing Chrysalin-based products and seeking other orthobiologic technologies that could compliment our development efforts. This alternative would clearly position OrthoLogic as a drug development company in several of the most promising segments of the orthopedics market. Furthermore, after the close of the sale, OrthoLogic is expected to have more than 120 million dollars in cash and cash equivalents, and no long-term debt. With this funding base, the company would have the resources necessary to fully develop the Chrysalin product platform and repaying for our shareholders, the potential long term value of the program. In addition, the company would be in a position to pursue other complimentary orthobiologic technology.

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After careful consideration, and after consultation with medical and financial industry experts, our board of directors decided OrthoLogic shareholders were likely to benefit most if we were to successfully pursue option three. The process was then put in place to ascertain whether or not we could sell the bone growth stimulation business for fair value. After extensive negotiations, we determined that the bone growth stimulation business could be sold for fair value, and have therefore pursued the course of action announced this morning.

To summarize then, we believe that this alternative allows us to focus exclusively on orthobiologics as a pure play without the distraction of simultaneously attempting to manage two very different businesses. Gives us the significant financial flexibility to pursue Chrysalin commercialization and explore complimentary technologies allows us to maintain a greater degree of control over the Chrysalin product platform, gives us the time necessary to better understand the long term value of the Chrysalin based technologies, and finally, provides greater clarity of OrthoLogic's vision for both our current stockholders and the investment community as a whole.

In closing, we believe that becoming an orthobiologic's pure play represents the most promising means for OrthoLogic to reach its strategic goals and create the greatest possible long term value for our stockholders.

With that, Operator, we will now open the call up for questions.

**Operator:**

Thank you. This floor is now open for questions. If you do have a question, please press the number one followed by four on your touchtone phone at this time. If at any point your question has been answered, you may remove yourself from the queue by pressing the pound key. We do ask that while you pose question that you please pick up your handset to provide optimum sound quality. Once again ladies and gentlemen, that is one followed by four on your touchtone phone at this time. One moment while I poll for questions. Your first question is coming from Bill Plovanic of First Albany. Please go ahead with your question.

**Bill Plovanic:**

Great, thank you. Can you hear me okay?

**Tom Trotter:**

Yes Bill. How are you today?

**Bill Plovanic:**

Good. Good morning Tom. Congratulations.

**Tom Trotter:**

Thank you sir.

**Bill Plovanic:**

Obviously now there's a shift in focus for the company, you're becoming a biotech play rather than a medtech play, and so the questions, I believe, are going to be focusing on that. I was wondering, you know, first and foremost, if you now shift all your focus on to being a biotech, I think a lot of the investors out there are curious as to kind of management experience historically in ushering a biotech product or drug through the approval process.

**Tom Trotter:**

That, that's a good question Bill. Well, I can tell you that our management team cumulatively probably has at least 50 years of experience in the medical business. I myself have been in the medical business, both on the device side and some experience on the drug side, for 27 years. Dr. Jim Ryaby, who is our Senior Vice President and Chief Technology Officer, has an extensive background in bone biology and the development of bone products, and is very familiar with all of the orthobiologic technology, both drug and device. In addition to the talent that we have in the company, we also have several consultants who are working with us, experts in the whole development of successful NDA strategy as well as managing the key aspects of NDA filings, and we are working regularly with them, and they are helping us formulate our strategies and our plans. In addition, we have managing our clinical trials a very strong individual, Maria Walker, who worked for the human genome sciences, and has 15 years of experience in managing human clinical trials. We're very confident, Bill, that the team that is here today is capable of taking the program forward to success.

**Bill Plovanic:**

Great. If I could ask a couple more questions. On the manufacturing of the products, for Chrysalin, are you able to manufacture enough material for the phase three clinical trials, and is that a scalable manufacturing process?

**Tom Trotter:**

Yes. Let me answer that. We actually have already produced the material necessary for the phase three clinical trials. We have gone through several developmental aspects of that, and they're very pleased with the work that's been done. This has been a collaborative effort between OrthoLogic and Chrysalis Biotechnology, and we've been working with a large outside manufacturer in the processing of the peptides. So from a scalable standpoint, we don't see any issues relative to managing that part of the process, and are very confident that we'll manage that effectively. But also say that a scale up of the manufacturing of a synthetic peptide product as compared to large molecule products, which have very complicated recombinant DNA technology, is very different, and we're very confident in our position.

**Bill Plovanic:**

Great. And actually that's it. I'll jump back in to queue.

**Tom Trotter:**

Thanks a lot.

**Operator:**

Thank you. Your next question is coming from Juston Cable of B Riley & Company. Please go ahead with your question.

**Justin Cable:**

Hey, good morning guys.

**Tom Trotter:**

Hi Justin.

**Justin Cable:**

So it looks like DJO has to raise some debt or refinance some current bank debt. Are there any concerns on your part number one, and then number two, what are the, I guess, the break up rates or I guess the potential break up fees if this thing does not go through?

**Tom Trotter:**

Yes, okay. Well, first of all, I'm not in a position to answer for DJO, and I would suggest that those who are interested be sure to listen to the conference call that will be coming up. I believe it's beginning at 11:00 AM pacific daylight time, 2:00 PM eastern standard time by Les Cross from the folks at Don Joy, and they'll be able to better answer your question relative to the particulars of the financing. But we have satisfied ourself, Justin, to a fairly exhaustive process that DJ has the capability to successfully complete this transaction. They will be raising the money, but we have gotten assurances through this process that have given us the comfort level that that will be successfully accomplished. I'm sorry, that was second part of the question?

**Justin Cable:**

Yeah.

**Tom Trotter:**

There are some break-up fees involved, and they will be detailed actually in the proxy statement, which will be coming out to all of the shareholders. All of the shareholders and those interested will also, of course, be able to see a copy of the definitive agreement or the asset purchase agreement, which will be filed with the SEC as part of our next filing, our next 10-Q filing. But just in summary, I would tell you that there's a two million dollar fee that OrthoLogic would owe to DJO if we are unable to get shareholder approval for the transaction. There is also a topping fee involved should a superior proposal come forward, and we also have a fee if there are certain operating parameters that are not met by DJ through the process, which would allow for them not to be able to close that would result in a break up fee. So again the details of that will be in the proxy, and I would direct your attention there.

**Justin Cable:**

Okay, fair enough. Well from a strategic standpoint it certainly makes sense that they would want this business because I know that they had some kind of stimulation technology that they were trying to use to compete, but it certainly makes sense that they would acquire this, and I guess judging by the stock price today and their stock, it's a positive reaction.



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Now on the same subject, have you had, or maybe you can talk about a little bit, have you talked to a number of other potential suitors for this business, just kind of give us a sense of what the interest level has been?

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**Tom Trotter:**

Yes. Again, I would direct everyone's attention to the proxy when it comes out because there will be a very detailed explanation there of the timeline and the process, but I can give you an overview. And that is that over the last 18 months to 24 months that we have been having discussions with folks, we have been talking to over 20 different companies, and through that process, four companies generated expressions of interest in the business. And through that process, we have concluded the transaction with DJO, or DJ Orthopedics, and that was at the highest value that was generated throughout that whole process.

**Justin Cable:**

Okay, that's good. One last question, perhaps this would be kind of a good forum to kind of talk about what you see as the competition for Chrysalin as of today or what you see as kind of in development stages right now for Chrysalin?

**Tom Trotter:**

Well I can make a couple of comments on that. I would prefer to take that question, Justin, at our upcoming conference call when Dr. Ryaby is here and can comment as well on that. But as of this time, and to our knowledge, the first of the Chrysalin based products, which is the product for acceleration of fracture repair, is the only product that is in U.S. clinical trials, in human clinical trials, in the United States. And I would tell you that I have been in the medical business, as I said, for 27 years, I have probably seen a handful of products in that entire time that have the capability or had to show the capability to change the practice of medicine. And the Chrysalin product for acceleration of fracture repair has the potential to change the practice of medicine. And when you have one of those products, should you be successful through the clinical trials in gaining approval, you reap a significant benefit in terms of sales and profitability from that. So we're very pleased and excited about our lead product, which is the fracture acceleration product in particular, and it's advanced state. In terms of competition for that product, to our knowledge as I said, a number of people have announced intentions to enter in to this arena. However to our knowledge, no one has yet gotten past the pre-clinical stage and entered human clinical trials. So we believe we have a significant lead over any of the other potential competitors for a fracture acceleration product. In the spinal fusion area, the Chrysalin product, as we detailed in the past, would be combined with commercially available allograft, and the resulting product, what we're hoping to show, is Chrysalin with commercially available allograft would be equal autograft in a spinal fusion procedure. And if that turns out to be the case, we believe it could have a significant competitive advantage versus large molecule products in spinal fusion today, which are on the market or in development. However, there are a host of products being developed in the spinal fusion arena, and it would take too much time to detail all the potential competitors.

The other point I would make, however, for the spinal fusion application, is that because of the very, very low cost of the Chrysalin technology, we believe, if we're successful and that product does enter the market, we would have a significant advantage in terms of cost of production, which is very important in the overall medical business today.

The third potential product that in development is, of course, for cartilage defect repair, and we have completed pre-clinical work with that, and we are, as we've said in previous conference calls, hopeful of beginning a human clinical trial on that early next year in the first half, perhaps, of 2004. And in that arena, there is no product today that has been really judged a success in terms of cartilage defect repair. There are products that are on the market, however, they all have complications, cost issues, and their rates of success have been less than people had hoped for. Our pre-clinical data, pre-clinical animal data for cartilage defect repair, which Dr. Ryaby presented at the World Cartilage Meeting in Toronto, was probably as good as anyone has seen in pre-clinical work in the rabbit models that were studied, and we're very enthusiastic about that.

So I guess if I summarize for you, I'd say that two of the three products we believe are potentially either leaders or in the lead in very substantial markets, and the spinal fusion product, while it has other competition, certainly already in the market and in development, would certainly have a cost profile that should make it a very competitive product.

**Justin Cable:**

Okay, great. One last question, and then I'll turn the call over to other callers. With so much cash on the balance sheet, would that help you speed up the development process of Chrysalin or are there no real changes as of today?

**Tom Trotter:**

Well frankly, that is one of the things that we are most excited about. We believe with the funding that is available, we will be able to take whatever steps are necessary to accelerate as much as possible the development of the Chrysalin product platform. And so our anticipation is some revisiting of our schedules and timings because, of course, we have been operating under a different set of outlooks given the position of the company and the cash position and so forth. So we are re-examining that. It is our intention to accelerate as much as possible the development of the entire platform.

**Justin Cable:**

Okay, thank you.

**Tom Trotter:**

Thank you.

**Operator:**

Thank you. Your next question is coming from Eric Miller of Hartland Advisors. Please go ahead with your question.

**Eric Miller:**

Yeah, congratulations Tom.

**Tom Trotter:**

Thank you Eric.

**Eric Miller:**

On the, again, as you said and actually you just talked about it, I was going to ask, you know, what steps could you take really to accelerate? I would assume the phase three fracture healing, there's really not much acceleration you could go on that one right now, but as potentially what more the spinal as well as the cartilage where you could speed up the time table a bit?

**Tom Trotter:**

Well, I think you have to look more broadly than that Eric. I think the issue is how fast could we arrive at a potential filing for a new drug application or an NDA. The Chrysalin trials for fracture repair and spinal fusion are already underway. We hope to have the human clinical trial beginning for cartilage next year, and we believe we have adequately powered those trials and have correct site selection, and I would tell you as of our last comment on this, our, we are on track with the enrollment in the human clinical trials that are underway. I think when we talk about acceleration of the program, I think what we're talking about, I'd like to make clear what we're talking about, is doing all the other potential things which are required to surround a successful NDA application, and perhaps doing more of those things on a simultaneous basis as opposed to a consecutive basis. And that can have the effect of potentially speeding up a potential NDA filing. And with the resources that we will have now, we have the potential to consider multiple other clinical trials or things that could help us accelerate the overall filing of the NDA.

**Eric Miller:**

Okay. How about on obviously now the issue now of a partner is less on the front burner. But I'm assuming eventually you'll need one for distribution. When, any timeframe of, you know, how long that's pushed back now?

**Tom Trotter:**

Okay, well I would want to be careful about characterizing anything as being less on the front burner. I would tell you that we are having on-going active discussions as up to date as last week with both pharmaceutical companies and orthopedic companies regarding potential partnerships on Chrysalin. I do not see, frankly, the change in the status of our company as in any way negatively impacting or slowing down any of those discussions. I think what's changed, Eric, is that we now sit at the table in a much stronger position than we were previously. And I think we also are in a position where we can be as sure and absolutely sure as possible that at the point in time when we decide that a partnership makes sense for Chrysalin, should we decide that, we're in the best position to negotiate the most favorable terms possible. I think I would also point out that as part of our licensing agreement with Chrysalis, which was filed as part of a former Q filing, we are required in the licensing agreement to have a partner, a corporate partner if you will, for the sales and marketing of the Chrysalin product by the time the first NDA has been filed for the first product outside the United States. That is not necessarily world wide, but the agreement is specific that there would be a partner to handle the product outside the United States. Now, so that is a commitment that's within the license agreement, and that would have to take place on or before the filing of the first NDA for the first indication. Now having said that, I would tell you that there is a lot of excitement about the Chrysalin peptide, and we believe that there is real value in considering a partnership for the Chrysalin program. And so I don't want to give anyone the impression that those discussions are going to stop or



are going to slow down. We're simply going to continue moving forward, and at the point in time that our board feels it's in the best interest of the shareholders to take that action, if we decide to do that, we will.

**Eric Miller:**

Okay, great. And just one last question. With all of the cash that you'll have after this deal, you do have an existing buy-back program on the books. And what's the board and your thought process about maybe accelerating that, doing the Dutch auction, something like that?

**Tom Trotter:**

That is true. We announced in March that we were instituting a share repurchase program. But let me say very clearly that the primary purpose for selling the bone stim business was to generate significant resources, which when added to the existing cash we would have, would put us in a really strong financial position to fully develop the Chrysalin product platform. And we need to be sure that we have adequately allowed for that. In addition, we think it's very important to broaden, potentially, our orthobiologic base since we are now a pure play orthobiologic company, or would be post transaction, and so that would be a second consideration for the funding. Now having said that, since we do have an existing stock buy back program in place, once the transaction has been completed, we may also choose to become more active in that area, and that would be a decision the board would make, as always, depending on market conditions.

**Eric Miller:**

Okay, thanks Tom.

**Operator:**

Thank you. Once again ladies and gentlemen, if you do have a question, please press the numbers one followed by four on your touchtone phone at this time. Your next question is a follow up question from Bill Plovanic of First Albany. Please go ahead sir.

**Bill Plovanic:**

Great, thank you. Tom, just some clarification on the spine trial that's going on right now, just is that a phase one, two, or is that a phase three trial? Can you refresh our memory?

**Tom Trotter:**

Yes. That was authorized by the FDA as a combined phase one, phase two trial, and just to clarify what that means, generally, phase one, phase two trial is primarily a safety trial where you are also looking for some preliminary indications of potential efficacy. Trials are not powered to in the phase one, phase two, generally speaking, to generate data which would be clinically significant or statistically significant, I'm sorry. So it is a combined phase one, phase two, Bill, primarily a safety trial with some potential of trend in efficacy is what is hoped for.

**Bill Plovanic:**

Okay. And if you could remind us on the royalty that's payable to Chrysalis. Is that a big royalty, small royalty, you know, as I look at the future of the company, I've got to try to figure out what the profitability is and what type of gross margin you would have once you're out there in the marketplace.

**Tom Trotter:**

Sure. Well, fortunately in the license agreement, the royalty is relatively small. It's something in the range of seven percent. And there is also a sliding scale on the royalty that that declines once the total royalties paid top a number, and I don't have that at my fingertips, but it's approximately 50 million I believe. It moves down to a lower number, and then up to 100 million, it changes again. So it scales down from nominally seven percent, Bill. There are also some milestone payments that would happen moving forward, and those now, since we have done most of the early filings and paid most of the early milestones, are primarily milestones tied to NDA submissions and NDA approval. And again, I believe the numbers are a million dollars or something in that neighborhood for an NDA submission, or two million, and four million dollars for NDA approval. Again, we'll give some more specifics on that. I would refer you to the, again, the agreement, which has been filed with the SEC and it's available in a Q, but again, the milestone payments and the royalties are fairly nominal given the potential of the product.

Now, for the other part of your question, and I think that is the key, Chrysalin is a small synthetic peptide, and our indications from the early studies we've looked at from a manufacturing perspective would suggest that we can put the Chrysalin product in its current embodiment in a syringe with saline for a very nominal cost, and would generate something in the neighborhood of a 90 percent gross margin.

**Bill Plovanic:**

Including the royalty?

**Tom Trotter:**

Perhaps a slightly less than that, I didn't know that was your question, but a little less than that. But certainly something north of 85 including the royalty.

**Bill Plovanic:**

Okay. And great. And then what, remind us, give us an idea of post this divestiture, what was your headcount prior to and what is your headcount going to be post the divestiture?

**Tom Trotter:**

Okay. The current OrthoLogic headcount is about 165 employees. Post the divestiture, the headcount would be something in the range of 25 to 30 employees.

**Bill Plovanic:**

Okay. And then if you could also remind us just, I'm kind of going back and forth, but you know we've talked on the surface about what pricing for Chrysalis would be when you upon approval understanding that the BNP's are going at four to five thousand, and it looks like they're tracking pretty well in to the marketplace. Do you think that you would be revising your expectations on pricing upward from where they had been previously?

**Tom Trotter:**

Well, I don't know Bill, that we would necessarily do that. We have said publicly in the past that we've been looking at the fracture acceleration product with a potential pricing in the range of 500 dollars for the injection. And again, that would be, to use your example, about one tenth the cost of bone morphogenic protein. However, at that price you would still, in our view, be carrying, as I mentioned, probably an 85 percent gross margin net of royalties. So that is our current thinking. Again, we have not established firm pricing on that. We have a fair amount more work to be concluded before we would make any definitive statement on that, but that's the ballpark number.

**Bill Plovanic:**

Great. And last point, last question is if we look at the long bone study, can you remind us what the endpoints are in that study?

**Tom Trotter:**

Yes. If you're referring to the ongoing phase three trial for acceleration of fracture repair, the endpoints in those studies, there are several of them. One of the endpoints is removal of immobilization or removal of the cast. Another would be pain, another is range of motion, there's several of them, and again, four, probably three or four at least endpoints in that study. And again, I apologize, if Jim were here he could rattle those off for you right away.

**Bill Plovanic:**

Right. Great, that's it. Thanks a lot Tom.

**Tom Trotter:**

Okay, thank you.

**Operator:**

Thank you. Your next question is coming Justin Ferayorni of Bricoleur Capital Management. Please go ahead.

**Justin Ferayorni:**

Morning. Congratulations guys.

**Tom Trotter:**

Thanks Justin.

**Justin Ferayorni:**

That's a great outcome. Bill asked my question about headcount, but did you refer to or give us some guidance on how long you think this transaction will take to close?

**Tom Trotter:**

Yes. That is, right now, there's several factors gating on that, but we're hopeful that the transaction would close perhaps by Thanksgiving at the earliest, and probably, hopefully by the end of this year on the outer side, although that is dependent, to a great extent, on the SEC. This will require OrthoLogic shareholder approval. We need to file the proxy with the SEC, the SEC has the ability to review that and make a judgment.

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So until we understand the date of the proxy filing, it's a little difficult to schedule the shareholder vote. But assuming normal processes Justin, we would hope that perhaps by Thanksgiving or early December we would have a close. There's also a Hart-Scott Rodino filing that would be required, however we don't anticipate any issue there. But that's our current thinking, and I think assuming a smooth process, that would be the outcome.

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**Justin Ferayorni:**

Great. And I assume Jim is going to be on your quarterly call, so we can get in to the more details about Chrysalin then? Is that correct?

**Tom Trotter:**

That s correct.

**Justin Ferayorni:**

Okay, great. Thanks again. Congratulations.

**Tom Trotter:**

Thank you.

**Operator:**

Thank you. Your next question is coming from Geoff Kuli of Essex Investment Management. Please go ahead with your question.

**Geoff Kuli:**

Hi. Can you please remind us what your operating expenses related to Chrysalin has been year-to-date?

**Tom Trotter:**

Well, yes. We can tell you that through the second quarter, which is what the information we have released, Sherry do you have that number?

**Sherry Sturman:**

Right. If you look up to the second quarter on R&D, we ve spent a little beyond four million on the Chrysalin process.

**Geoff Kuli:**

Okay.

**Tom Trotter:**

And we have given guidance, I believe, for the year, and the analysts have been estimating that the Chrysalin investment this year would be in the range of nine million dollars.

**Geoff Kuli:**

Okay. And is there anything in SG&A?

**Tom Trotter:**

Well, we of course have SG&A in the company, but again, we have not broken out the model for the new drug development company, and we will be discussing that on our next conference call.

**Geoff Kuli:**

Okay, but any of the SG&A through the first six months of the year, could that be, are you saying that it s impossible to allocate that to Chrysalin versus (inaudible)?

**Tom Trotter:**

We do not do segment reporting between the Chrysalin program and our device business, and again, with that said information, our SG&A has been a total SG&A for OrthoLogic. We will give some guidance, as I said, on our next conference call in a couple of weeks as to what we expect will be the not only just the cost of Chrysalin programs, but the drug development company on a go forward basis.

**Geoff Kuli:**

Thank you.

**Operator:**

Thank you. Your next question is coming from Weidong Huang of Times Square Capital. Please go ahead with your question.

**Weidong Huang:**

Hi. Could you give us some timeline on the completion of the phase three trial in fracture repair as well as the phase one slash two trial in spinal fusion, when we should be seeing some results?



**Tom Trotter:**

Yes, I can at least tell you what we have been, we have publicly acknowledged on those questions. On the phase three trial, we have indicated that based on our targeted enrollment, we would hope to complete enrollment for that trial next summer, is our target. There is a six month follow up, actually a 12 month follow up, but we would believe we would have most of the patients healed after the six month timeframe. So it is probably an issue of early 05 before that data would be available, that is in the ongoing phase three trial for fracture acceleration. Now, I would also point out, we have powered that trial for a potential interim look, and that would be taken after half of the patients have been enrolled and completed the follow up. That trial is approximately 500 patients. We anticipate that we might be in a position to take an interim look at the data should we choose to do so

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in the second half of next year. So perhaps in the late summer, early Fall of next year, we may be in a position to do that and have something to say about that on the phase three trial.

On the phase one, phase two trial for spinal fusion, that trial we have indicated will likely be the end of next year, 2004, before the enrollment would be completed, and that trial has a nine month follow up. So it's unlikely that we would see data out of that trial before probably late '05 in that timeframe.

**Weidong Huang:**

Okay. How about your expectation on having an international partner in place. Do you expect that to happen before you have the results of those two trials?

**Tom Trotter:**

Well again, we have not publicly stated that we are going to partner on the Chrysalin program, other than to fulfill our obligations as I outlined them under the Chrysalis agreement, which does not require us to do so until the filing of our first NDA application. Having said that, we do have ongoing discussions at this time, and depending upon those discussions and the outcome of those discussions, our board will make a decision at any point in time relative to the potential partner on the program. So we do not have a set timeframe for that other than the back end obligation I mentioned relative to the licensing agreement.

**Weidong Huang:** Okay. Going back to your earlier comments about the human safety data, can you give us a little bit more color maybe as to the overall efficacy and safety data that you have gathered so far on Chrysalin?

**Tom Trotter:**

Well I can make a general statement about that, but mostly I would direct your attention that that information is publicly available. There was a phase one, phase two human clinical trial that was completed on the fracture acceleration product. That data was presented at the American Society for Surgery of the Hands. It was a year ago last October, 2002 in Phoenix, and I believe an abstract from that presentation is available, and as well as information relative to preliminary efficacy. But in general, I would tell you that there have been no safety issues associated with the Chrysalin peptide or no adverse events associated with the Chrysalin peptide in the trials to date, both that trial and a separate phase one, phase two diabetic ulcer trial that was completed by Chrysalis Biotechnology a little earlier, and their data has also been provided at, I believe it was a wound healing conference in Spring, I think, of 2002. But that data is available, it's publicly available, and I would direct you there to answer your question more fully. However having said that, in our phase one, phase two trial, we did not see any safety issues attributable or adverse events attributable to the Chrysalin peptide, and we also saw preliminary evidence of acceleration of fracture healing. And again the specifics of the data are available in those presentations.

**Operator:**

Thank you. Your next question is a follow up from Bill Plovanic of First Albany. Please go ahead sir.

**Bill Plovanic:**

Three things, just on the phase one, two spinal (inaudible), the end of the enrollment is '04, nine month follow up, and then I assume that we're going to have to do a phase three trial after that.

**Tom Trotter:**

Well that is not necessarily conclusive Bill. I think one of the things that this, the new platform, if you will, of the company, the new orthobiologics company, will have the potential to do, is to begin potentially a second trial either in the United States or potentially even in Europe looking at the spinal fusion, the spinal fusion indications. So again, this would be an example of where we may be able to do additional trials, not necessarily anything beyond a phase one, phase two, but until that was successfully completed, but additional trials simultaneously with the ongoing trial. And that has some impact then on your discussions with the FDA as to what sort of trial you would have to do beyond that. So normally you would take the data from the phase one, phase two as we did with the fracture acceleration product, and have your meetings with the FDA following the conclusion of the trial and the follow up, and gain authorization or attempt to gain authorization to begin a phase three.

**Bill Plovanic:**

Okay. But you would think with a pivotal phase three in spine that when you do do that, you're going to have to have two year follow up because, you know, my understanding that's kind of the gold standard with the FDA for spinal study.

**Tom Trotter:**

Well again, I would direct that question to Dr. Ryaby, and he is not here this morning, but I would tell you that drugs are treated differently than devices Bill, and while it has been true that the device side of the business, products going through the PMA process from an ID to a PMA have required, the FDA has required two year follow up for a device for spinal fusion, I'm not sure that that is the same for the drug side.

**Bill Plovanic:**

And then just remind me, the difference between a drug and a device in the labeling and the marketing?

**Tom Trotter:**

Well that's a fairly significant difference, and I think it's a very key important difference that we think will be very important in the orthobiologics business moving forward. And the difference is this, if you have a device approved by the FDA as a medical device that is, comes out of a PMA, a successful PMA, you are not allowed to advertise the method of action of the product. You can simply state this is what our product did compared to the placebo group. You're not allowed to discuss method of action. When you get a drug approved by the FDA, you are allowed to discuss method of action, and this is in your advertising and your promotion. And we believe this is going to be a key pivotal point going forward in the world of orthobiologics, to be able to sit down with the surgeons and explain to them what the method of action is that actually creates the effect as opposed to just saying this is how this device did versus people who didn't have it. So we think that is going to be a significant marketing advantage and one of the things that we're most excited about.

**Bill Plovanic:**

Is there also an expanded labeling with a drug versus device?

**Tom Trotter:**

Well again, it depends on the product. Typically, I would tell you that devices coming out of the FDA through the PMA process are approved as indication-specific devices. However, drugs do not generally come out indication-specific. The example I have typically used is to look at the difference between a product such as Synvisc, which was approved for osteoarthritis of the knee as a device, and that is its approval for osteoarthritis of the knee as a device. If you look at Celebrex by comparison, which came out of the FDA as a drug, it is approved for arthritis anywhere in the body. It happens to have a very significant effect in osteoarthritis. So you potentially get broader labeling as you come out of the FDA as a drug versus a device, and we think this could be particularly important for us going forward as well.

**Operator:**

Thank you. Our last question for today is coming from Steve Emerson of Emerson Investment. Please go ahead with your question.

**Steve Emerson:**

Are you ready at this time to possibly give us ballparks as to your accelerated burn rate for '04/'05, and of course, the follow up question is what kind of acceleration in your timeline, let's say for spine, well for your three areas, is reasonably possible with an accelerated spending?

**Tom Trotter:**

Okay. Thanks for your question Steve. As I mentioned earlier in the call, the purpose of this call was not to get in to the burn rates for the potential orthobiologic company going forward. This was simply to explain the transaction announced today. We will address the question of burn rate for certainly the balance of this year and '04 on our next scheduled conference call, and I'll simply have to delay the answer until that time. We are re-evaluating these things, and we want to be sure that we give the best possible information, and we think that in a couple of weeks we'll have that for you.

On the types of things we can do to accelerate the potential NDA filings and NDA approvals, I've also alluded to those. There are a number of aspects of a successful NDA filing that, fit, if you will, with the pieces of the puzzle together. And there are things that can be done simultaneously and things that have to be done sequentially. There's toxicology studies, there's pharmacokinetic studies, there are dosing studies, there's a whole series of things that are done to support a successful NDA filing. And in our former capacity, as we were managing this program, it was necessary for us to do some of these things on a sequential basis rather than a simultaneous basis. And what I was alluding to this morning is that this funding does provide us the opportunity to consider doing simultaneously some of those things which could have a positive impact on the date of the filing of NDA and NDA submission.

**Steve Emerson:**

Well perhaps in your spinal fusion work, is there an interim look which you could then take to the FDA and perhaps start your phase three s earlier, perhaps by a year than you had hoped. That kind of thing.

**Tom Trotter:**

Yes. Unfortunately Steve, the phase one, phase two trial for spinal fusion was not powered to take an interim look. It was powered to give us what we believe would be good evidence or the best evidence we could get of indication of safety and some preliminary indication on efficacy. It was not powered for an interim look.

**Steve Emerson:**

Thank you.

**Tom Trotter:**

Thank you very much. I think Larry, does that bring us to a conclusion. Operator, we will now, I think, close the questions and answers, and I will make a closing statement.

I d just like to thank everybody again this morning for taking the time to visit with us. We realize that this is a significant change in the future OrthoLogic, but one that our board is confident is in the best interest of the shareholders. We believe very strongly in the potential of the Chrysalin product platform, and as I stated earlier in my comments, we believe products like Chrysalin, particularly for the fracture repair product, have the potential to change the practice of medicine. And we feel this is going to be a very exciting development program, and we are looking forward to giving you a further update on all of this in a couple of weeks on our conference call. I would also point out that on Tuesday, the 21st of October at 8:00 AM, Dr. Ryaby and I will be presenting at the Techvest conference in Boston, and that will be webcast. And if you re interested in additional information about the program, we will be providing some updates at that meeting as well. So thank you very much for joining us today, and have a good day.

**Operator:**

Thank you. This does conclude today s teleconference. You may disconnect your lines at this time, and have a wonderful day.