
MANAGEMENT DISCUSSION SECTION

Operator: Good day, everyone, and welcome to the Alphatec Spine Incorporated Conference Call. Today's conference is being recorded. At this time, I would like to turn the conference over to Ms. Cheryl Monblatt. Ms. Monblatt, please go ahead, ma'am.

Cheryl B. Monblatt, Director, Investor Relations

Thank you and good morning, everyone. Welcome to Alphatec Spine's conference call to discuss our preliminary third quarter 2008 revenues and other corporate events. With me today are, Dirk Kuyper, President and Chief Executive Officer; Peter Wulff, Chief Financial Officer; and Eburn Garner, General Counsel.

By now, you should have all seen a copy of today's press release. If you do not have a copy of the press release, you can find it in the Investor Relations section of our website at www.alphatecspine.com. Before we start, there are a couple of items we'd like to cover.

I would like to remind you that this call is being webcast live and recorded. A replay of this event will be available later today on our website, and will remain available for at least 30 days following the call. We'd like to remind you that our discussions today include forward-looking statements. These statements are based on certain assumptions made by us based on historical trends, current conditions, expected future developments, including business prospects, product development objectives and future financial performance, and other factors we believe to be appropriate in the circumstances.

Risks and uncertainties may cause our actual results to differ materially from those projected in these forward-looking statements. You can find a discussion of these factors and more information about us in our filings with the SEC, including the Risk Factor section on our Form 10-K for 2007 as amended, subsequent quarterly report on Form 10-Q and periodic filings on Form 8-K.

These forward-looking statements are made as of the date of this call, and we assume no obligation to update these statements publicly, even if new information becomes available in the future. This broadcast is covered by U.S. copyright laws and any use or rebroadcast of all or any portion of this conference call may only be done with our express written permission.

I'll now hand the call over to Dirk Kuyper, Alphatec Spine's President and CEO.

Dirk Kuyper, President and Chief Executive Officer

Thank you, Cheryl. Good morning, everyone, and thank you for joining us today.

As you can see from the press release, we have a lot of news that we're very excited to share. We proudly announced preliminary record quarterly revenues of 25.8 million for the third quarter of 2008, representing approximately a 27% increase over revenue for the same period last year. This is the fifth consecutive quarter of increased revenue.

In the U.S., we grew third quarter 2008 revenues by approximately 28% over last year's quarterly revenues, representing a sequential acceleration of our core business growth. For the nine months ending September 2008, revenue will be reported at a record amount of 72.9 million, an increase of 24% over revenue from the prior year's nine months.

It is significant to note that we were able to grow our core business at a rate greater than the spine market prior to the launch of any of our new products under development that are focused

specifically on treating disorders of the aging spine. As a result of this growth, we are raising our 2008 annual revenue guidance from 95 million to 100 million, an increase of 25% over 2007 revenue.

We're extremely excited about the upcoming North American Spine Society meeting that will be held in Toronto, Canada this week. NASS is one of the premier spine industry medical conferences, where surgeons from around the world come for peer-to-peer training, to view new techniques and learn about innovative products. We are offering live presentations and hands-on workshops, given by leading surgeons at our booth throughout the three days of the show, emphasizing our shift to a more scientific and education oriented company.

We also announced today the unveiling of our new corporate brand, 'Solutions for the Aging Spine' and the launch of nine new products at the NASS meeting in Toronto. They are as follows. The OsseoFix Spinal Reduction System, which is being launched in the European Union, and the following products which will be launched in the U.S, the OsseoFix+ Cement Vertebroplasty System for Vertebral Compression Fracture Fixation; the Novel Cervical Interbody implant system; the ProFUSE Demineralized Bone Scaffold; the Vacuum Infusion Packaging for use with the ProFUSE Scaffold; the Illico Minimally Invasive Retractor and Cannulated Screw System; the Zodiac ROC Lumbar Fixation System, which is a revamped next generation of this product; Posterior Disc Prep Set; and the Novel Corpectomy Set.

The new products launching at NASS show our dedication to developing new and innovative products to complete our full line of surgical products, and these products will help us to maintain our current growth rate into 2009. In addition, over the weekend we also launched our new corporate website, which we invite you to visit at www.alphatecspine.com.

Now, I'd like to update you on the development of the OsseoFix Spinal Reduction System. We've received a European CE Mark for the OsseoFix System, which allows us to market OsseoFix in the European Union for treatment of spinal compression fractures. This will be launched in conjunction with OsseoFix+ Cement, which already has CE Mark approval. Commercial launch in Europe is expected to commence during the fall of 2008, and we'll begin training European surgeons on the use of the OsseoFix System during the NASS meeting.

As previously announced, we're also conducting a 30-patient clinical study in Germany. After the completion of the study, study results will be submitted for publication in a peer reviewed spine journal.

In addition, following recent constructive conversations between the U.S. Food and Drug Administration and us, the FDA has asked us to conduct a clinical study of the OsseoFix System to support the 510(k) application that we filed in June of 2008. Exact details related to the parameters and timing of the study are presently being discussed with the FDA, and we will provide an update on the study and the anticipated launch date of OsseoFix in the U.S. once such discussions are complete.

It is our understanding the FDA is requiring all new vertebral augmentation devices to complete a study to support a 510(k) application. As we were already planning a clinical launch at approximately 20 study sites following receipt of FDA clearance, we are well prepared for this study and already have a draft clinical study protocol, which should allow us to complete the requirements with the FDA and get to the study quickly.

Early patient results from Europe have been extremely encouraging and we are confident the U.S. study will provide us with additional clinical data that will substantiate the benefits of OsseoFix. We look forward to the full commercial launch of OsseoFix in the European Union as the lead innovative lead product to propel our European business.

Currently, the two most common procedures used to treat vertebral compression fractures are kyphoplasty and vertebroplasty. The current 2008 U.S. market size for compression fractures is estimated to be \$850 million. We designed and developed OsseoFix and OsseoFix+ to allow us to compete in both segments of the market, with what we believe to be improvements over the most common products being used today.

The OsseoFix system is designed to allow for improved fracture reduction and to use less cement during a surgical procedure, both of which we believe reduces the risk of cement extravasation, reduces surgical complications and increases clinical efficacy.

The OsseoFix+ system has an improved opacity for visualization of the cement under imaging, a self-contained mixing chamber for fume reductions in the operating room, and a superior delivery system for cement introduction.

In terms of other products, update on the OsseoScrew System, our unique pedicle screw solution for dealing with patients with poor bone quality, we're making solid progress on the development of the product, as the screw is currently undergoing biomechanical testing. We are extremely excited about the potential opportunity, market opportunity for OsseoScrew. In the U.S. alone, there are expected to be 280,000 thoracolumbar fixation procedures this year. We estimate the U.S. market opportunity, therefore, for OsseoScrew to be almost \$2 billion. We plan to submit a 510(k) for OsseoScrew System to the FDA by the end of the year, subject to conclusion of the biomechanical testing, which is currently ongoing.

As mentioned in our prior discussion, this past June we released our comprehensive Illico MIS Retractor System and more recently released the complementary MIS Cannulated Screw System, which allows us now to compete in 80% of all minimally invasive procedures. Complementing the Illico MIS platform solution will be our next-generation minimally invasive access system called GLIF.

The GLIF is a breakthrough access system that provides a far lateral approach to the spine, with the patient in a natural face down position. The GLIF is designed to allow surgeons to perform a 360-degree minimally invasive procedure without the need for repositioning the patient, which may reduce the length of time of the procedure, reduce the trauma and reduce post-operative recovery period. We'll be providing a – and we're well on track with that product.

We will be providing a full financial overview of the third quarter results in early November, and we'll provide the time and date for that shortly. At that time we'll provide additional details on the status of other development projects. As previously stated, our goal has been to achieve and sustain an above-market growth rate of 20% in the U.S., with our core products and to layer in aging spine products on top of that for additional growth.

We are extremely pleased to have exceeded this goal and are confident that we can sustain our growth rate going forward. We will achieve this by continuing to focus on sales force expansion and upgrades, moving to an exclusive distribution network, and by continuing a core product release cadence that expands our line into the future.

The Alphatec team has done a phenomenal job in the last year and the results are evident in our ability to take market share and to release significant new products on time. With the completion of the rebranding at NASS, we look forward to bringing our aging spine products to market and continuing to deliver exceptional growth and opportunity to our investors.

Cheryl B. Monblatt, Director, Investor Relations

Thank you. Go ahead. Operator?

QUESTION AND ANSWER SECTION

Operator: Thank you, ma'am. [Operator Instructions]. And for our first question, we go to Vivian Cervantes with Rodman & Renshaw.

<Q – Vivian Cervantes>: Hi, good morning. Thank you for taking the question. Understanding that the FDA is now requiring data to support 510(k) submissions for vertebral augmentation products, what are your thoughts about something similar being required for thoracolumbar products, in particular OsseoScrew?

<A – Dirk Kuyper>: Good morning, Vivian. That's actually a very good question, and our intention is to submit the OsseoScrew as a pedicle screw and be very careful about not trying to go for additional claims right upfront. We don't want to get into the same discussion, obviously. And then clinical work after the fact, we would go back then to try to expand the indication.

<Q – Vivian Cervantes>: Okay. So if I go back now to the OsseoFix, given that you're still working with the FDA on timing and such, would it be unreasonable to assume a likely one quarter delay?

<A – Dirk Kuyper>: We're still negotiating obviously the number of patients and the timeline. We had anticipated obviously originally launching OsseoFix in this quarter.

<Q – Vivian Cervantes>: All right.

<A – Dirk Kuyper>: And I think the delay would be longer than that. Our anticipation, it's about a year.

<Q – Vivian Cervantes>: Okay. With OsseoScrew though again, your approach that it's going to be a pedicle screw submission, I'm just concerned that there could be some push back given some similarities with bone cements injection and support. Would it be – what are your thoughts about maybe delaying submission for OsseoScrew with maybe some data behind it?

<A – Dirk Kuyper>: We're currently working on the data and we're evaluating all of those. We're also evaluating the performance of the screw without cement.

<Q – Vivian Cervantes>: Okay.

<A – Dirk Kuyper>: And then we'll make a decision, once we have all of the data, but we're evaluating all of those alternatives.

<Q – Vivian Cervantes>: Understood. Which is why the biomechanic testing is going at full force at this point.

<A – Dirk Kuyper>: Exactly.

<Q – Vivian Cervantes>: Okay. Terrific. Thank you for taking the question.

Operator: And we go next to Bill Plovanic with Canaccord Adams.

<Q – William Plovanic>: Great. Thank you. Good morning.

<A – Dirk Kuyper>: Good morning.

<Q – William Plovanic>: Actually, my first question is going to be for Peter. I know this is just a preliminary release of the top line numbers. But can you give us any color on what the U.S. and O.U.S. split is just so we can get a feel for kind of traction in those different geographies?

<A – Peter Wulff>: Good morning, Bill, and good morning everybody else. The breakout for the quarterly revenues represents about a 28% growth year over prior year quarter for the United States, and then about --

<Q – William Plovanic>: 28?

<A – Peter C. Wulff>: 28, yes.

<Q – William Plovanic>: Excellent.

<A – Peter Wulff>: And approximately 10% growth quarter over prior year quarter for the Asian market.

<Q – William Plovanic>: Okay, that's very helpful. Thank you.

<A – Peter Wulff>: Yes, welcome.

<Q – William Plovanic>: And then just on – since we're on numbers and guidance, if I look at the numbers, and we looked at the guidance, I don't know if you've given official guidance for '09. I know we are looking for 20% growth. Obviously, OsseoFix would have been a contributor for that. Sorry, it's Monday morning. If you could just give us some commentary on what your [inaudible] now that you have to do a whole new study for OsseoFix and kind of what – how you think about next year now, if you are willing to answer that at this point?

<A – Dirk Kuyper>: Yes, it's – as I mentioned from my remarks, our goal has been to have a greater than 20% growth rate in our core products, and obviously at 28% we're exceeding that. And with the release of the new products, we see no reason why we can't continue to grow certainly well above 20% going forward, even with the delay in OsseoFix. So the way we viewed OsseoFix and OsseoScrew were really products that would then go on top of that sort of normal company growth rate to get us to more of a hyper growth scenario. So that's obviously delayed a little bit, although we are speeding up the development of OsseoScrew and GLIF in order to compensate for that, but we feel extremely confident about our ability to sustain a greater than 20% growth rate just in the core products.

<Q – William Plovanic>: And then when you say accelerating the OsseoScrew, I think previously you are targeting like a March approval launch. Would – should we still expect that or are we looking more at an early first quarter for that product at this point, barring any challenges?

<A – Dirk Kuyper>: I would still use that timeframe, the sort of end of first quarter.

<Q – William Plovanic>: Okay. And then one last question, I'll jump and let other people on. Just in the German study, you mentioned there's 20 patients. Where are you in the enrollment of that study at this point, and what's the longest follow-up you have on any patient?

<A – Dirk Kuyper>: It's actually 30 patients, and the study protocol is for a six-month follow-up. The first patient was done in – I believe it was August, I believe early August. So we're coming close to 2.5, coming close to three months on the first patient.

<Q – William Plovanic>: And then are you fully enrolled or where are you in enrollment on that?

<A – Dirk Kuyper>: No. We'd have to get an update on that, but we're still early. We are training two additional German surgeons at the upcoming meeting, so that should speed things up quite a bit. One is Karen Buttner-Janz from the Charite Hospital in Berlin and the other is a surgeon out of the north near Hamburg named Solas. And so with the addition of those two, we should – we hope

to speed up the enrolment. The criteria in Germany for doing kyphoplasty or vertebroplasty is a little stricter, and so you are really dependent on the patients coming in.

<Q – William Plovanic>: Okay. And actually one last question, I promise, and that's it. Given the fact that now you're going to have to do an incremental study for the OsseoFix here in the U.S, would that change your thinking on what your R&D spend will be as we head into '09?

<A – Dirk Kuyper>: No, I don't think so. We had actually already planned to do a post-launch study, and so we had already budgeted and factored that into the '09 plan. So we don't see it as having any impact in terms of where we believe we're going to end up in '09. And yet on the positive side, obviously any time you do a FDA sponsored study, it's an opportunity to recruit and attract new surgeons, who then hopefully will use other products that are in our bag. So we actually work to the opportunity to get some incremental revenue out of this.

<Q – William Plovanic>: Great. Okay, thanks a lot guys. See you later this week.

<A – Dirk Kuyper>: Okay, thanks.

<A – Peter Wulff>: Thank you, Bill.

Operator: And for our next question, we go to Julie Hoggatt with Noble Financial.

<Q – Julie Hoggatt>: Hi, guys. Thanks for taking my question. Dirk, my question is for you. In the draft clinical study that you mentioned for OsseoFix, can you tell me how large is the study and how long the follow-up is?

<A – Dirk Kuyper>: Well, we're – that is in negotiations with the FDA, so we're trying not to necessarily comment. But we believe that there is a very short follow-up time period required for this. Obviously, we need to convince the FDA of what our belief is. If you're asking what our original study protocol was, it was six months. But we need to – we've not agreed to that with the FDA at this point, we want it as short as possible. And the number of patients that we were going to do in the study originally was 200, but we believe that's significantly more than what the FDA will require.

<Q – Julie Hoggatt>: Okay, that's very helpful. Thank you. And in terms of – you had mentioned increasing your sales force, can you give us an idea if you increased any this quarter and to what number you are at this point?

<A – Dirk Kuyper>: Yes. Hold on, let me – yeah, we've – in the second quarter, we had a total of about 206 sales people. We are now, as the end of the third quarter, up to 221. And the percentage of exclusive continues to move up, it's about 65% at this point.

<Q – Julie Hoggatt>: Thank you so much. I'll jump back in queue.

<A – Dirk Kuyper>: Okay, thanks.

Operator: For our next question, we go to Bruce Jackson with RBC Capital Markets.

<Q – Bruce Jackson>: Hi, Dirk.

<A – Dirk Kuyper>: Hi, Bruce. How are you?

<Q – Bruce Jackson>: I'm good. With regard to the OsseoFix protocol, you said you already had the draft protocol in place. What are the types of parameters that you already have set and how much do you think might have to change after discussions with the FDA, and how quickly do you think you could get the study going after you get the green light?

<A – Dirk Kuyper>: Well, we think we can get the study going very quickly. The longest time period, to be honest, probably will be at each individual site. We're going to need to get IRB approval to conduct the study. And that generally, depending on how often the hospital's IRB meets, that may take a little bit of time. So that's probably the gating item to be honest with you.

Our protocol was put together with a number of clinicians. What probably will be negotiated is sort of the endpoints and exactly what we want to prove out. We have the opportunity here to make a decision between equivalents and potentially some secondary endpoints, which might show superiority. So those are things that we have to discuss with the FDA and understand how it might change things.

But in general, the protocol itself, I think will be very consistent with what the FDA wants. So it may be really just sort of the endpoint and sort of the timing follow-up period that we're going to need to negotiate with them. So our goal is to have all of that completed as quickly as possible then start. We already have the sites that we have pre-selected. We're already in discussions with them. So as soon as we have the protocol approved by the FDA, we'll be going back to those sites to begin the process of getting IRB approval to start the trial.

<Q – Bruce Jackson>: Okay, that's great. Then with regard to the core growth rate, it's quite good. And I was wondering how much of that is due to the sales force expansion, and how much is due to the new products? And then a follow-up to the sales force expansion question, do you expect to continue expanding the sales force and raising the exclusivity?

<A – Dirk Kuyper>: Yes. I mean our goal is clearly to get to a totally exclusive sales force in the U.S., so we will be continuing that move into next year. We are continuing to both expand and upgrade our sales organization. There is a number of opportunities in the marketplace with some of the latest things going on that have provided us some very unique opportunities in some areas where we did not have very strong distribution at this point. So we're working through those situations. So we do see also a continued expansion into 2009 of the overall sales force.

In terms of the growth, if you think about sort of where we've come from, one, we've launched a couple of products back at NASS last year, one of them being the TRESTLE Cervical Plate. That obviously we're benefiting from, it's performing extremely well in the marketplace. We revamped Zodiac and several of our other products, so they are certainly contributing. But up until this meeting, there hasn't been a huge number of new products releasing to the market.

So that's why we feel very, very comfortable with our ability to continue our growth rate going into the next year, because we continue to build the sales force but also now we have a nice bolus of new products sort of hitting the sales force that should help us to continue to grow our business. And we plan now in the spring also having – there's – we've set a cadence now where twice a year we expect to release a number of products in the core product area. And we will do that this spring as well, so in order to maintain that core growth rate.

<Q – Bruce Jackson>: All right, that's very helpful. Thank you.

<A – Dirk Kuyper>: Thank You.

Operator: And with a follow-up question, we return to Bill – I apologize – Plovanic with Canaccord Adams.

<Q – William Plovanic>: Okay, don't hurt yourself. Just two last questions, OsseoFix in Japan, any update you'd like to give there, Dirk?

<A – Dirk Kuyper>: Well, that is a long-term process as well . I'm sure you know that getting through the MHLW is – takes some time. We were in Japan recently and we met with several key clinicians who are advisors to the MHLW, and we're going to need to do a study there as well. And so we're in the process of working through those details. But that – I suspect that will take longer than the US study to complete.

<Q – William Plovanic>: Okay. And then any update on Europe you would like to give us? I think I might be stealing all the thunder of the third quarter call here, but just how is the Greek business doing, and then have you signed any other distributor as yet that are starting to stock?

<A – Dirk Kuyper>: Yeah. In the third quarter, we recognized our first European revenue, so we actually were paid the first installment from the Greek distributor. So we recognized close to \$0.5 million in revenue out of Europe, which is very encouraging. In the meantime, we have signed a second contract for another European country, which I think we'll save that for the third quarter call, and we've got several more very close and in discussion, what we're finding is a tremendous excitement for OsseoFix. So we think we're going to be able to accelerate our ability to sign up distributors now, already the Greeks in particular, and several others that were sort of on the fence have indicated a very strong interest in OsseoFix in getting going quickly. So we're extremely encouraged by that.

<Q – William Plovanic>: Okay, great. And then an assumption I would make as you put up a very strong year-over-year growth in the U.S., I think this is your best quarter even on a tough comp quarter. Is it fair to assume that you are likely to see some leverage and the operating losses come down as you really lever that U.S. platform?

<A – Peter Wulff>: Good morning, Bill. With the growth rate that we have here, we are very encouraged to see that we are able to deliver with the core business. The guidance that we have does not change in terms of what we expect in early '09 to turn into EBITDA positive statistics and then also for earnings per share positive as well. So what we can do later in the early November earnings call is provide more color for you all there as you see the full disclosures then for our third quarter P&L performance and year-to-date P&L performance.

<Q – William Plovanic>: Okay, great. Thank you very much.

<A – Dirk Kuyper>: Thanks, Bill.

Operator: Also with a follow-up question, we return to Vivian Cervantes with Rodman & Renshaw.

<Q – Vivian Cervantes>: Hi, thank you. Just a quick follow-up question. Given the solid results for the quarter, just wanted to get your thoughts on the macro environment and how that might be impacting your business?

<A – Dirk Kuyper>: Healthcare in general tends to be a pretty good defensive position, and obviously demographics work in our favor. As people age, obviously there is more need for spine surgery. Also what we see is, there is a fair amount of disruption in the marketplace. Some of the small companies out there, the venture backed ones, are starting frankly to dry up. They have no ability to raise additional funds, and so we actually see a very fertile environment for ourselves going forward, and we are trying to take those opportunities as they come up. So I think for Alphatec, I think it's actually a fairly positive environment and it gives us lot of opportunity.

<Q – Vivian Cervantes>: Great, thank you.

Operator: And also with a follow-up question, we return to Bruce Jackson with RBC Capital Markets.

<Q – Bruce Jackson>: Hi, just a quick follow-up on the OsseoFix study. Given the changes, is there any change to the budgeting for that study?

<A – Dirk Kuyper>: That's a good question, Bruce. We have to flush. Obviously, that is somewhat dependent on the FDA, you know where we end up negotiating with them in terms of amount of follow up and timing. But as I mentioned, we had put a fairly significant amount into the – built into the budget for this large, post-launch study that we planned on doing for publication. So we feel pretty good that we probably have most of that covered. Again, we'll have to see as it unfolds over the next few weeks, but I don't see any significant risk there. I think we are well covered with what we had already anticipated.

<Q – Bruce Jackson>: All right. Thank you.

<A – Dirk Kuyper>: Okay. Thank you.

Operator: And with that, ladies and gentlemen, we have no further questions on our roster. Therefore Mr. Kuyper, I'll turn the conference back over to you for any closing remarks.

Dirk Kuyper, President and Chief Executive Officer

Okay. I want to thank everyone for joining us on the call this morning, obviously a very exciting time for Alphatec. We are extremely pleased with the third quarter revenue results. We do think it's an indication of what we've been able to achieve, and we believe we have now the distribution network and the products in place to continue to drive above 20% growth in the U.S. going forward.

We are very excited about our rebranding and the product releases at NASS. Hopefully a number of you will be attending and we urge you to come by to see just how much the company has changed. So we feel very good about the future, about where we are at, and look forward to giving you more details during our third quarter call coming up in November. Thank you very much.

Operator: And ladies and gentlemen, this does conclude the Alphatec Spine Incorporated conference call. We do appreciate your participation, and you may disconnect at this time.

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