Intersect ENT Inc.

Fourth Quarter and Full Year 2015 Earnings Conference Call

Tuesday, February 23, 2016, 4:30 PM Eastern

CORPORATE PARTICIPANTS

Lisa Earnhardt - *President and Chief Executive Officer*

Jeri Hilleman - *Chief Financial Officer*

PRESENTATION

Operator
Good afternoon, and welcome to the Intersect ENT Fourth Quarter and Full Year 2015 Earnings Conference Call. All participants will be in listen-only mode. All participants will be in listen-only mode. Should you need assistance, please signal a conference specialist by pressing the "*" key followed by "0." After today's presentation, there will be an opportunity to ask questions. Please note this event is being recorded.

I would now like to turn the conference over to Jeri Hilleman, Chief Financial Officer. Please go ahead.

Jeri Hilleman
Thank you, Laura. With me today is Lisa Earnhardt, our President and CEO. We appreciate you joining us today to review our fourth quarter and full year 2015 results and business update.

Before we begin, I'd like to remind you that we will make statements during this call that include forward-looking statements within the meaning of Federal Securities laws. Actual results and timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties, which include without limitation; our outlook for financial performance, sales force growth, clinical studies, approval of new products and indications and procurement of reimbursement codes, which are based upon our current estimates and assumptions, as well as other risks detailed from time-to-time in Intersect ENT's reports filed with the SEC. Intersect ENT disclaims any obligation or undertaking to update or revise any forward-looking statements contained herein.

I will now turn the call over to Lisa Earnhardt. Lisa.

Lisa Earnhardt
Thanks Jeri and good afternoon, everyone. 2015 was a remarkable year for Intersect ENT, and we are very pleased with our achievements, as measured by both commercial results and advancement of our pipeline. We exited the year with our strongest quarter ever, with over 100,000 patients having received the benefit of PROPEL in their sinus surgeries to-date. Throughout the year, we added consistently between 130 and 150 new accounts a quarter, bringing our total account base to just under 2,000 accounts. We are now working with about one in three accounts, and approximately one in four ENTs or otolaryngologists.

We believe our success in 2015 sets the stage for continuing growth in 2016, as our team focuses on increasing market penetration and physician adoption, and on advancing our pipeline of new products. With regard to market penetration, we are pleased that almost one out of 10 patients undergoing sinus surgery now receives PROPEL. As expected, our market penetration varies throughout the country.

With regard to our clinical pipeline, 2015 was a productive year, as we work toward expanding indications and our product offering. In 2015, we completed the PROGRESS trial, assessing the safety and efficacy of PROPEL mini, when used following frontal sinus surgery. The study met its primary endpoint, demonstrating a statistically significant 38% relative reduction in the need for post-operative interventions. Based on these findings, we filed the PMA supplement with the FDA in September, and believe that we will receive approval this quarter.

We also started enrolment of a pivotal study for the NOVA steroid releasing implant, as well as continued enrolment of the pivotal trial for the RESOLVE implant. Enrolment for both trials is going exceptionally well, and I am pleased to share that we now expect to complete enrolment for both trials earlier than previously communicated with PROGRESS NOVA enrolment now expected to be completed by the end of this quarter, and RESOLVE II by mid-2016. Our timeline for potential approval of these products remains in line with previous guidance, with NOVA in 2017 and RESOLVE in 2018.

As we look towards our 2016 commercial goals, we continue to expect to achieve $78 million to $80 million in revenue. This outlook is supported by several specific drivers of growth, including first, increasing sales force tenure, as reps gain maturity in their territory, following the significant expansion we undertook last year. Second, the late 2015 edition of sales consultants to help drive higher utilization of PROPEL. Third, the expected approval of the frontal indication for PROPEL mini. And finally, effective January 1st, increased reimbursement for the FESS procedure.

To touch on each of these drivers, I will start first with our sales team. In line with our communicated plans, we grew our sales force from 52 territory managers at the start of the year, to 74 at year end. Given promotions of some to management as well as turnover, exactly half of our territory managers joined us in 2015. As these reps gain tenure and others continue to grow, we would expect to see an increase in leverage, or a per rep productivity, as we progress in the year.

In addition, we now have 20 sales consultants in place to provide greater physician support. Most of these sales consultants were in training in Q4, and we look forward to seeing their impact grow over the course of 2016. This year, we do plan only limited expansion of our sales force. We maintain our view that the appropriate size sales force for the surgical facing market falls in the 75 to 100 rep range. At this point, with our territory managers and sales consultants, we are effectively at critical mass, so we can now focus our team on leverage.

Our third driver of growth is the expected approval of the frontal indication for PROPEL mini, which offers the benefit of expanding the addressable market, and providing clinical outcomes data that reinforce the overall benefits of PROPEL. We estimate that approximately 25% to 30% of the over half a million sinus surgeries a year involve the frontal sinus. If approved, this would allow us to promote such use not only to existing PROPEL customers, but also to physicians, who to this point, have not found a role for PROPEL in their practice.

One further driver to 2016 growth is the increase in the CMS reimbursement rate for the FESS procedure that became effective at the start of the year. Despite our strong clinical evidence, at times, physicians do limit their use of PROPEL due to costs. Therefore, we consider the increased reimbursement rates a meaningful opportunity to engage both physicians and administrators, in discussions about increasing the role of PROPEL in their practice.

Finally, although this is a longer term driver of growth, I would also like to highlight our efforts towards international commercialization, as we were very pleased that the German Institute for the Hospital Remuneration System has assigned a status one reimbursement, the highest level for PROPEL. This reimbursement only applies to the 11 hospitals that submitted applications in 2015, but it is a gating step, and one on which we will build on the next few years. We are also actively working in Japan, and secondarily China, to define our regulatory path forward.

I will now turn the call over to Jeri, to discuss our recent financial results and outlook. Jeri.

Jeri Hilleman
Thank you, Lisa. Our fourth quarter revenues were $18.8 million, a 40% increase over revenues in the fourth quarter of 2014. Our annual revenues were $61.6 million, a 60% increase over the year 2014. We continue to see significant contributions from new accounts, with about 40% of our year-over-year growth coming from new accounts; and we also continue to see strong recurring revenue, with about 88% of our revenue from reordering accounts.

Looking back at these periods, we accomplished a great deal. Our productivity in the seasonally high fourth quarter, was an annualized $1 million revenue per territory manager, in both 2014 and 2015. Our productivity per territory manager for years, 2014 and 2015, within the range of $900,000. Putting these together, our takeaway is that we were able to double the size of our sales force, while keeping productivity per territory manager relatively constant.

As we look to our 2016 growth, at our guidance target of $78 million to $88 million [see correction below], and with the addition of five or so territory managers, we expect to see a continuing rise in territory manager productivity. We expect this leverage to be supported by our 2016 growth drivers, including, as Lisa said, sales force tenure, the addition of sales consultants, the expected approval of the frontal indication for PROPEL mini, and the expanded procedure reimbursement.

[CORRECTION: The statement made in the immediately above paragraph during the earnings call on February 23rd, 2016, that Intersect ENT forecast revenue for fiscal year 2016 to be between $78 and $88 million, was a misstatement and is incorrect. Consistent with the other two statements of guidance during the call and with the guidance provided in the Intersect ENT press release dated January 11th, 2016, the Company forecasts revenue for fiscal year 2016 to be between $78 and $80 million.]

For 2016, we also continue to expect to see seasonal variation in procedure volume, with the low point in Q3 and high point in Q4. We have seen its historic procedure volumes drop by at least 10% in Q1 compared with Q4, and we expect our revenue to be impacted accordingly.

Switching to gross margin, our gross margin for 2015 was 80% versus 74% in 2014. This increase was achieved through a combination of expanded volume, spreading the overhead component and gains in efficiency. We expect to continue to improve gross margin slightly, expecting to see 2016 gross margin at 80% to 81%, as we expand to make growing product sales.

Our 2015 operating expenses totaled $76 million, including $4.9 million in stock-based expense. As in 2014, 22% of our expense went to R&D, including our clinical development efforts, and 78% to SG&A. Key drivers of overall expense included our headcount growth, especially in sales; expansion of our clinical development efforts, and G&A associated with being a public company.

Looking toward 2016, we would expect to see a similar split between R&D and SG&A, and total operating expenses of approximately $92 million, including approximately $8 million of stock-based expense.

Finally, our cash balance at year end was $124.3 million, representing a net use of cash during the year of approximately $20 million. Based on our financial guidance specifics, we would expect a net use of cash during 2016, in the order of magnitude of about $25 million.

That concludes our financial narrative today. Lisa, let me turn the call back to you.

Lisa Earnhardt
Thanks Jeri. We certainly navigated significant growth in 2015, our first full year as a public company. Now that the dust has settled on last year, a year full of long hours, inevitable challenges, substantial change and lots of learning, we are proud of all that we have accomplished. More importantly, I am proud of the team. Their focused determination and hard work are remarkable, and they never failed to keep the patient first in all we do. We are excited about 2016 and the significant milestones ahead, and remain committed to our vision of providing innovative solutions to chronic sinusitis patients across the continuum of care.

With that, Jeri and I will remain on the line to answer questions. Laura, let's go ahead and open up lines.

QUESTION AND ANSWER

Operator
Thank you. We will now begin the question and answer session. To ask a question, you may press "*" then "1" on your touchtone phone. If you are using a speakerphone, please pickup your handset before pressing the keys, to withdraw your question, please press "*" then "2." At this time, we will pause momentarily to assemble our roster.

Our first question will come from Mike Weinstein of JP Morgan.

Mike Weinstein
Thank you. And guys you covered a lot of ground very quickly there. Couple of items that I just want to circle back on, if we can. So number one, on the frontal indication for PROPEL mini, are you still hoping that comes through this quarter, and could you talk about that impact on current PROPEL usage? Thanks.

Lisa Earnhardt
Yes Mike, great to hear from you. And you are right. We do anticipate approval for the frontal mini indication, yes, this quarter. And so, we are looking forward to launching that new indication. About 25% to 30% of all patients undergoing sinus surgery have their frontals treated. So we think it's a really just fantastic opportunity, both to drive adoption with our existing users, to expand the pool of patients that they believe will benefit from our products. But then also a chance to reengage physicians who maybe haven't found a role for PROPEL in their practice. So we really think there are a number of different drivers for us, as we think about launching this. And the third thing is, really thinking about, this is another set of high level clinical data. So once again, prospective randomized trial, it actually had some nuances, where the choice of control is different, and in this case, it's randomized to nothing, which really is the standard-of-care in the frontal. So it's another data source, which really does corroborate the incredible amount of evidence we have for the benefits of PROPEL. So really across the board, we are very much looking forward to approval of the new indication.

Mike Weinstein
Okay. And you gave a very encouraging update on the pipeline; with those, the PROGRESS trial, to NOVA completing tests within this quarter, and RESOLVE II by the middle of the year; you kept your timelines for approvals unchanged. Is that just conservatism, because you want to see the date and get in front of the FDA? I assume there is nothing else there, rather than just being conservative?

Lisa Earnhardt
Yes. And I think once we have the top line data, and we understand the merits of that and how it will impact potential approvals, as we get closer to approvals, we feel like we will provide more specificity. But at this point, 2017 and 2018 are great places to plan for.

Mike Weinstein
Okay. And maybe just remind people, given that the pull forward of the enrolment in those trials, when we might see data from each?

Lisa Earnhardt
Yes. So for the progress in NOVA trial, we expect data…top-line data to read out midyear. And then for RESOLVE II, likely late 2016, early 2017 in terms of that top line data.

Mike Weinstein
Okay. And RESOLVE is obviously the one that's, because of the regulatory past, a bit more uncertain in terms of the turnaround time at the agency, is that fair?

Lisa Earnhardt
Yes. I mean, as you know, what's going down the drug pathway, and so that timeline, typically is a little bit longer in terms of approval for an NDA.

Mike Weinstein
Okay. And last question, I will let someone else jump in; so as we are into early part of 2016, anything different about this year, seasonality versus prior year seasonality? Obviously, we typically see some drop-off in elective procedures in 4Q to 1Q. Anything looked different so far this year, versus, last year, or the year before?

Lisa Earnhardt
Nope.

Mike Weinstein
Okay. That's very helpful. Thank you, guys.

Lisa Earnhardt
Great, thanks Mike.

Jeri Hilleman
Thanks Mike.

Operator
And our next question will come from Bob Hopkins of Bank of America Merrill Lynch.

Brad Mas
Hey guys, this is actually Brad in for Bob. Just two quick ones, one, wondering if you could talk about how you see the frontal indication driving the units per procedure? And where you think that can go from the current probably two, as well, I assume it didn't move much this quarter?

Lisa Earnhardt
Yes. Good question Brad. You are correct. I mean, we are looking right now around two implants per procedure, with our current indication in the ethmoid. We do anticipate a small

pickup there, but as we think about planning, we really think about the frontal indication as an opportunity to expand the number of patients being treated, more than simply increasing the implants per patient.

Brad Mas
Okay. That's helpful.

Jeri Hilleman
Just to reinforce that, yes, we expect the number of stents per procedure to stay roughly even in the near term.

Brad Mas
Okay. And then, can you just talk about…you gave some numbers about profitability per territory manager, can you just give some sense on where you guys think that can go at a peak, and how long you expect it to get there with the new shift in the territories?

Jeri Hilleman
I think we have given you some idea of what we achieved last year, expect for this year. We would expect to see productivity per territory manager going up. There is a couple of dynamics. As we go into 2017 and then 2018, we will be adding an incremental product to the bag. We would also probably continue to build our sales force up to, in total, closer to 125 reps, as we start adding the in-office. So there is a couple of dynamics on that. For the current place we are at with PROPEL, we have seen territories go up to $1.4 million, $1.5 million. We have often split the territories at that point, so we haven't really tested to see how high we can get in productivity. But on average, we do expect to see the continued build, roughly 10% from 2015 into 2016.

Brad Mas
Okay, that's very helpful. And then just last one, can you talk about pricing for PROPEL next year? Do you expect it to be stable again?

Jeri Hilleman
Well, we did do an increase of around 3% from 2014 into 2015. We did that again from 2015 into 2016. It seems to be in line with industry practices. We haven't formulated our specific plans for 2017 yet.

Brad Mas
Great. Thanks guys.

Operator
Next, we have a question from Thomas Gunderson of Piper Jaffray.

Kyle Bauser
Hi good afternoon. It's actually Kyle on for Tom. It sounds like the second cohort of the PROGRESS trial to evaluate, or use of NOVA in the frontals its progressing nicely, in which you expect top line results sooner than expected. But could you provide sort of any updated details on the C2 trials for in office use of NOVA, so the trial size, enrolment completion data, et cetera.

Lisa Earnhardt
Yes, Kyle. Thanks for the question. At this point, our focus for NOVA is much like we do with PROPEL, it’s getting our initial approval, and then we will consider potential follow-on studies.

So we have just decided with all the clinical programs we have ongoing this year, it's best to focus our efforts on getting PROGRESS, NOVA across the finish line and getting the NOVA product approved. And at that point, we will look at additional studies for that product.

Kyle Bauser
Okay. And congratulations on receiving status one from your NUB application on the first try. You mentioned that a limited number of participating hospitals or 11 will be able to receive reimbursement for PROPEL. How long you think it will take to start seeing a material impact of sales from U.S. reimbursement?

Lisa Earnhardt
It's going to be a few years. We would expect Germany to build at a fairly slow pace. We will look at other countries. We have regulatory considerations we have to work through in Asia. So it's going to be a few years before we start seeing material revenue from overseas.

Kyle Bauser
Okay. Thanks, and then just lastly, the annual rep productivity is about $900,000 and you are reaching sort of critical mass, at least, in terms of territory managers for the surgical market. But any update to how long it takes for the average rep to get to that $900,000 market, and what are some of the highest productivity levels you are seeing amongst your sales force?

Lisa Earnhardt
Yes, it is really varying on how long it takes for an average rep to get up to that level. And we are still continuing to learn. We split territories last year; we added a lot of new ones in. Historically, it always took about nine months. I think in many cases, we are seeing it take a little bit longer than that. In terms of peak productivity, again, we tend to split the territories around $1.4 million, $1.5 million. So that's about the peak we have seen, but again, we did cap it by splitting the territories.

Kyle Bauser
Alright, great. Thanks. That's it for me.

Lisa Earnhardt
Okay. Thank you.

Operator
The next question is from Richard Newitter of Leerink Partners.

Ravi Misra
Hi good afternoon. This is Ravi in for Rich. Can you hear me okay?

Lisa Earnhardt
Yes. Hi Ravi.

Ravi Misra
Hi. How are you doing? So a couple of questions, shuffling between calls, so forgive me if I am asking something twice. First, if I get to start on the sales force, you are saying that 125 is the sort of boldest sort of…I am sorry, when you are getting the in-office product in, how should we

think about hiring around that, or is that going to be pre-hired before approval in 2017, or should we think about hiring in line with your launch strategy?

Lisa Earnhardt
Yes. We really think that's something that will build over the course of 2017 and 2018, to meet the needs of the office demand. And this year, as we commented on the call, just very sort of modest additions, given that we are already at critical mass, we believe, with the 74 territory managers plus 20 sales consultants for the surgical opportunity. And we would expect, as I said, between 2017 and 2018, to start to build up to a greater number, to take advantage of the office opportunities.

Ravi Misra
And are these, are you sort of anticipating…I know it's early, but would you anticipate similar productivity versus the surgical opportunity or higher or lower? Any color on that would be helpful?

Lisa Earnhardt
Yes. We are really looking at it being the same sales force. So just as a reminder, you are calling on the same customer it's merely a different sight of care, if you will, going from the hospital or the ASC to the clinic. And so, we would anticipate driving increase in productivity over time.

Ravi Misra
Great, thanks. And then, on reimbursement, could you just maybe remind us of the timing strategy, is that still a 2018 event, and what are sort of the steps that you have been taking so far?

Lisa Earnhardt
And as you know, and you have probably heard me say ad nauseam. I do think reimbursement is a multiyear, multi-step process. So we haven't commented on a specific date. What we are really looking at is ensuring by the time we have both of our office products on the market, that we have reimbursement in place to ensure that physicians and patients have access. So reimbursement is both sort of coding, and then also working on the coverage. And those are all very much in the works. So in the next couple of years, I think, we will be well positioned to take advantage of those opportunities.

Ravi Misra
Great. And then maybe, one or two more. In Germany you have that NUB status; I mean, what's the launch date on that? I mean, have you guys begun to sell products in that area? And number two, did you give gross margin guidance on the call for 2016? Thanks.

Lisa Earnhardt
Yes. With regard to Germany, we are working through some logistics of it. We will probably start selling at some point potentially this year, and it would be at a very small level, and will build over time. But again, something we are kind of working through. We did give gross margin guidance for 80% to 81% for 2016.

Ravi Misra
Great. Thanks so much.

Operator
Again, if you would like to ask a question please press "*" then "1" at this time. Our next question will come from Kyle Rose of Canaccord Genuity.

Ryan Zimmerman
Hi, good afternoon, this is actually Ryan on for Kyle. Can you hear me okay?

Lisa Earnhardt
Yes. Hi Ryan.

Ryan Zimmerman
Hi. So just to go back to the frontal indication a bit, I understand how the 25% to 30% of all cases, including frontal sinus. Should we expect additional reimbursement for the frontal sinus indication, and ultimately longer term, would there be an additional opportunity for codes, for that frontal sinus indication?

Lisa Earnhardt
Yes, Ryan, much like with the ethmoid indication, use of PROPEL mini in the frontal would be intended to be covered by the existing FESS reimbursement code. So the codes that…and the reimbursement that the hospitals or surgery centers get for the procedure would be intended to cover that. So there wouldn't be sort of specific codes, other than the codes that currently in coverage, other than those that currently exist.

Over time, you would anticipate potentially, in the office setting, having codes specifically designed for the physician for the implantation. But really, we don't anticipate new reimbursement in the facility setting.

Ryan Zimmerman
Okay. Great, and thinking about the guidance for this year, $78 million to $80 million, when we think about the drivers of that outperformance, utilization, sales rep productivity, possibly reimbursement. In terms of those drivers, is there one that drives the outperformance in the quarter, or that really moves it ahead of the needle?

Lisa Earnhardt
No. We really think of all those between this; increasing sales force tenure, addition of the sales consultants, approval, potential approval of the frontal indication, and then the increased reimbursement, are all significant drivers for us this year, and we are excited to have so many things going in our favor.

Ryan Zimmerman
Okay. Great. That's it from me. Thank you.

Jeri Hilleman
Thank you, Ryan.

Operator
And this concludes our question-and-answer session. I would like to turn the conference back over to Lisa Earnhardt for any closing remarks.

CONCLUSION

Lisa Earnhardt
Great. Thank you all for joining us today. We certainly appreciate your interest and support, and look forward to staying in touch with you all. Thanks so much.

Operator
The conference has now concluded. Thank you for attending today's presentation. You may now disconnect.