AXOGEN

Second Quarter 2016 Earnings Call

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Operator: Greetings, and welcome to the AxoGen Inc. Second Quarter 2016 Results Conference Call.

At this time, all participants are in a listen-only mode. A question-and-answer session will follow the formal presentation. If anyone should require operator assistance during the conference, please press star, zero on your telephone keypad. As a reminder, this conference is being recorded.

It is now my pleasure to introduce your host Patrick Till of Investor Relations. Thank you. You may begin.

Mr. Patrick Till: Thank you, operator, and good afternoon, everyone. Thank you for joining us today for the AxoGen conference call to discuss the financial results for the second quarter ended June 30, 2016.

Today's call is being broadcast live via webcast, which is available on the AxoGen website. Within an hour following the end of the live call, a replay will be available on the company's website at www.axogeninc.com, under Investors.

Before we get started, I'd like to remind you that, during the course of this conference call, the company will make projections and forward-looking statements regarding the future events. We encourage you to review the company's past and future filings with the SEC, including without limitation, the company's Forms 10-K and 10-Q, which identify the specific factors that may cause actual results or events to differ materially from those described in these forward-looking statements. These factors may include, without limitation, statements regarding the product acquisition and/or development, product potential, regulatory environment, sales and marketing strategies, capital resources or operating performance.

And with that, I'd like to turn the call over to Karen Zaderej, President and Chief Executive Officer of AxoGen. Karen?

Ms. Karen Zaderej: Thanks, Patrick, and good afternoon, everyone. Welcome to our second quarter 2016 conference call. Joining me on the call today is AxoGen's Chief Financial Officer, Pete Mariani. Additionally, our call today was opened by Patrick Till of the Trout Group, who are now serving as our new Investor Relations firm. I'm sure many of you know the Trout Group, and we're pleased to have them join the AxoGen team.

I would like to begin today's call with a review of our second quarter highlights, followed by a brief company overview and an update on our key strategic initiatives. Pete will then provide a review of our second quarter financial results and updated guidance, after which time, we'll open it up to Q&A.

Now, turning to the quarter, revenue was 10.4 million, and was up 4 million or 62 percent over the prior year. We are especially excited as this marks our first ever quarter with revenue above 10 million and marks our 22nd consecutive quarter of year-over-year double-digit revenue growth.

The execution of our strategic initiative is continuing to deliver solid results. Our revenue growth reflects the expanding penetration and adoption of AxoGen's portfolio of products in the repair of nerve injuries. The growing demand is a direct result of increased market awareness, surgeon education, and our solid sales execution.

Our growth is driven by deeper penetration into our existing accounts as well as the development of new accounts. This progress is reinforcing AxoGen's position as a preeminent choice for surgeons when considering nerve repair.

We generated 4 million of revenue growth over Q2 2015. The majority of this growth was generated from active accounts. We define active accounts as those that have developed a certain level of consistency in their utilization of the AxoGen portfolio of products. These accounts have typically gone through the committee approval process, have at least one surgeon who's converted a portion of his or her treatment algorithms of nerve repair to the AxoGen portfolio and are ordering AxoGen products at least six times in the last twelve months. The number of active account has increased 42 percent to 374, up from 264 in the prior year.

The growing number and penetration of active accounts is driven by increased adoption of our nerve repair products across the surgeons' treatment algorithms. Accounts that are ordering all three of our nerve repair products continue to generate approximately five times more revenue than an account ordering just one product. Our objective is to continue expanding the treatment algorithms of surgeons to include all three of our nerve repair products across their full continuum of nerve repair.

For those of you who are new to our story, AxoGen is a global leader in innovative surgical solutions for peripheral nerve injuries and the only company focused solely on the nerve repair market. We currently have four products in our portfolio. Avance Nerve Graft is the only commercially available processed nerve allograft used for the bridging of nerve gaps of five millimeters to 70 millimeters.

AxoGuard Nerve Connector is the only minimally processed porcine extracellular matrix implant for connector-assisted coaptation of transected nerves with gaps of five millimeter or less. AxoGuard Nerve Protector is a minimally processed porcine extracellular matrix implant for wrapping and protecting injured peripheral nerves. We have also recently launched the AcroVal Neurosensory & Motor Testing System, which allows clinicians to evaluate nerve function through measurement, mapping, and monitoring prior to and following nerve repair.

Our products are used primarily by plastic surgeons, hand surgeons, and maxillofacial surgeons in a wide variety of nerve repair surgeries, including upper extremity and facial trauma and third molar extraction, as well as nerve compression surgeries involving recurrent carpal tunnel injuries.

AxoGen is generating strong and consistent revenue growth in a nerve repair market that remains largely untapped. There are approximately 900,000 nerve repair surgeries annually in the U.S., pointing to a market opportunity of over $1.6 billion for AxoGen's products. The vast majority of these procedures are being performed in approximately 5,100 centers.

In the second quarter, 374 of these centers were active accounts. And as a result, we believe we are just scratching the surface of our available market potential.

We are continuing to develop this market through the execution of our strategic initiatives, which we believe will allow us to build long-term sustainable growth. We refer to these strategic initiatives as our five pillars of growth - number one, build market awareness, number two, educate surgeons and develop advocates, number three, grow the body of clinical evidence, number four, execute on our sales plan, and number five, introduce and expand new products and markets in nerve repair.

Let me review our recent activities around each of these pillars. First, we're building market awareness by engaging with surgeons at hospitals, clinical conferences, and promotional events. Events such as these facilitate enthusiastic peer-to-peer interactions where surgeons can share and validate treatment algorithms and discuss outcomes around nerve injuries and repair solutions.

During the quarter, we exhibited at the Federation of European Societies for Surgery of the Hand in Spain. Additionally, we sponsored two full-day surgeon led training events prior to the meeting and a panel meeting during--a panel discussion during the meeting. All of these peer-to-peer forums continue to elevate the discussion around nerve repair and AxoGen's role as a preeminent solution provider.

Our second pillar of growth is focused on surgeon education and the development of surgeon advocates. We have developed and continue to conduct large national education courses, supplemented with regional and local events. These courses are surgeon led and are focused on the review of clinical data and emerging best practices in nerve repair, including the use of AxoGen products. Year-to-date, we've hosted six national courses, reaching a total of 165 surgeons.

We had previously announced, we would conduct a total of 12 national courses in 2016. Given the success of these programs and the increasing demand from surgeons, we have decided to conduct an additional national course this year for a total of 13, up from nine courses in 2015.

These courses allow surgeons to gain additional confidence in nerve repair best practices and drive adoption and increased utilization of our portfolio of products. In fact, this increased utilization is driving average annualized revenue in accounts of surgeons who have completed these courses to over 100 percent, six months following the completion of the course.

Our third pillar is to grow the body of clinical evidence. Our sponsored clinical project Ranger and Recon are active and enrolling. Recon, our Phase 3 pivotal study comparing Avance Nerve Graft to manufactured conduits in digital nerve injuries continues to enroll and is a long-term study to support the transition of Avance Nerve Graft to a biologic.

Our sponsored Ranger study is the largest multi-center study in peripheral nerve repair, with over 900 Avance Nerve repairs. We have supplemented this study with our MATCH study, which provides contemporary controls of Autograft and Manufactured Conduits. These studies continue to produce important data that is being shared at conferences and in peer-reviewed publications.

During second quarter, we had two separate presentations of Ranger data at the Federation of European Societies for Surgery of the Hand meeting in Spain. The first presentation compared outcomes in mixed nerve injuries up to 70 millimeters in length, repaired with either Avance

Nerve Graft or the historical standard nerve Autograft, which is nerve transplanted from somewhere else in the patient's own body. Both groups compared favorably, with reported outcomes of greater than 80 percent meaningful recovery. In this challenging patient population, Avance Nerve Graft provided patients the opportunity for nerve repair without the downside cost and comorbidities of sacrificing a functioning nerve.

The second presentation reported on comparative outcomes for Avance Nerve Graft and Manufactured Conduits in sensory nerve repairs. This study reported that Avance Nerve Graft returned a higher level of sensation and in more subjects than seen in the manufactured conduit group. This data reinforces the growing adoption of Avance Nerve Graft as an alternative to both Autograft and Manufactured Conduits.

Year-to-date, there have been 11 separate presentations of data on AxoGen products, four of which are studies from independent investigators. Additionally, this year, there have been six peer-reviewed publications on the AxoGen portfolio of products. We now have a total of 38 separate peer-reviewed publications, which continue to reinforce the growing body of evidence of AxoGen products and nerve repair.

Our fourth pillar is solid sales execution. We continued to deliver strong and consistent sales growth. Our growing sales organization is solidly executing on driving strong revenue growth from our active accounts as well as opening new accounts. We ended the quarter with 44 direct sales reps, of which 29 have now been with us for at least 12 months.

In addition to direct sales force, we have 23 independent distribution partners supporting the execution of our sales strategy. We now expect to have at least 50 direct sales reps in the U.S. by year-end 2016, as we continue to focus on key territories.

Our fifth pillar is the introduction and expansion of new products and markets in nerve repair. Last quarter, we announced the launch of AcroVal Neurosensory & Motor Testing System, a nerve function evaluation system for surgeons and other allied health professionals to electronically measure, map, and monitor patients with peripheral nerve injuries and conditions, both prior to and following nerve repair.

As we stated previously, AcroVal's direct contribution to AxoGen's revenue growth is expected to be relatively minor. However, it strengthens our position in providing peripheral nerve solutions, and we believe it is an important step to support the standardized evaluation and measurement of nerve function to improve patient peripheral nerve outcomes.

We believe there are additional opportunities to expand peripheral nerve repair, and we will launch one additional nerve repair product yet this year. Although the upper extremity and oral maxillofacial markets are our prime revenue sources today, expansion opportunities in head and neck surgery, urology, breast reconstruction, lower extremity, and the pain market offer AxoGen new and expanded revenue opportunities in the future.

Together, the execution of these pillars have allowed us to consistently increase the penetration of our existing accounts while also growing our customer base. We are pleased with the progress we're making with each of these pillars, and we believe that this progress is allowing us to develop the foundation for long-term sustainable revenue growth. The work we're doing clearly demonstrates that we're developing the market of nerve repair and AxoGen is becoming the preeminent nerve repair company.

I'll now turn the call over to Pete, who will provide you with additional details about the second quarter results Pete?

Mr. Peter Mariani: Thanks, Karen.

In the second quarter of 2016, revenue was 10.4 million, an increase of 4 million or 62 percent over the prior year. The growth in revenue was primarily the result of increases in unit volume as well as price. As in prior quarters, the majority of our revenue growth is driven by growth in active accounts. Additionally, we continue to see growth in our pipeline of new accounts, as surgeons become familiar with our products and begin to develop their treatment algorithms.

Gross profit in the second quarter was 8.9 million, an increase of 65 percent compared to 5.4 million in the prior year second quarter. Gross margin was 85.2 percent compared to 83.8 percent in the prior year. The year-over-year increase was driven by growth in unit volume, operational efficiencies and price increases. We have now completed the transition of our processing facility to Dayton, Ohio and are running at expected levels.

Total operating expenses in the second quarter were 10.5 million, up 39 percent over the prior year, as we continue to make important investments in pursuit of our strategic initiatives. These investments include expanding our sales footprint, increasing physician education, expanding market awareness, and developing future products. These investments are driving growth in the company's operating expenses, but importantly, at a lower rate than sales growth, demonstrating the operating leverage in our business model.

Sales and marketing expenses in the second quarter were 6.8 million, up 41 percent or $2 million over the prior year. As a percentage of revenue, sales and marketing expenses decreased to 65 percent compared to 75 percent in the prior year. As Karen mentioned, we ended the quarter with 44 direct sales reps, up from 32 in the second quarter of 2015.

Year-to-date, we have now completed six national education courses compared to four in the prior year. Given the success and demand of these events, we have decided to schedule an additional course in the year, and we will now conduct 13 of these courses in the calendar year compared to nine last year.

R&D spending in the second quarter was $937,000, an increase of 27 percent over prior year. Research and development cost include product development as well as additional expenditures in our clinical efforts, which are substantially focused on our ongoing RECON study in support of our biologic license application, or BLA, for the Avance Nerve Graft.

In the second quarter, general and administrative expenses were 2.7 million, up 38 percent over the prior year. The increase was primarily the result of increased employee compensation, which included a $272,000 non-cash charge related to contingent stock options in the quarter. As a percentage of revenue, general and administrative expenses improved to 26.4 percent in the quarter compared to 30.9 percent in the prior year.

EBITDA loss in the quarter improved to 1.5 million compared to a loss of 2.1 million in the prior year. EBITDA is a non-GAAP financial measure and is defined as earnings before interest, income taxes, depreciation and amortization. This is a measure that is commonly used by institutional and other investors and could be helpful to assess operational performance and liquidity, excluding the impact of debt and fixed and intangible assets.

Net loss in the quarter was $2.8 million or 9 cents per share compared to 3.2 million or 13 cents per share in the prior year. We ended the second quarter with 18.3 million in cash compared to 20.9 million at the end of the first quarter of 2016.

Our use of cash in the quarter improved to 2.7 million compared to 3.6 million in the second quarter of 2015 and 5 million in the first quarter of 2016. As a reminder, our Q1 '16 use of cash included 1.5 million of strategic investments around the transfer and expansion of our processing and distribution centers and the payout of our 2015 all employee annual bonus.

Excluding the impact of these items, our use of cash in the first quarter would have been 3.5 million. The reduction in our--in the use of cash in the second quarter demonstrates our ability to drive top line revenue growth while also developing efficiencies across the business. We expect to continue to see improvements in quarterly EBITDA and use of our cash as revenue increases.

The execution of our strategic initiatives is continuing to deliver solid results. And with 18.3 million in cash on the balance sheet at the end of the quarter, we remain confident that we have sufficient cash to reach profitability while still investing in the company's growth initiatives.

Finally, as we disclosed in our release today, uh, we increased our full-year 2016 revenue guidance to over 40 million, and we are also increasing our full-year 2016 gross margin guidance to exceed 80 percent.

And with that, I'd like to hand the call back over to Karen.

Ms. Karen Zaderej: Thanks, Pete.

Before we close, I'd like to highlight a few additional items. First, we were very pleased to have been included in the Russell 2000 Index in June. We believe that being a part of the Russell 2000 should continue to increase our exposure within the investment community and broaden our investor base.

Additionally, we are pleased to announce three Investor Events in the coming months. August 17th, we will be presenting at the Wedbush conference in New York City. September 28th, we will be hosting a small Investor Event at the American Society of Surgery for the Hand in Austin, Texas. And November 21st, we will be hosting our first Investor and Analyst Day in New York City.

The Investor Events in Austin and New York City will include a review of clinical data and best practices in the repair of peripheral nerves from key opinion leaders as well as an opportunity to interact with the AxoGen leadership team. More detailed information about these events will be available on our website and announced in upcoming releases.

In closing, our efforts to expand market awareness, surgeon education and enhanced sales execution are allowing us to increase both the number and penetration of our accounts and deliver solid results. Along with our additional initiatives to help develop clinical evidence, new products and new markets, we are reinforcing our position as the preeminent nerve repair company and building a foundation for long-term sustainable growth.

Before taking questions, I want to thank our investors for their continued support and all of the members of the AxoGen team for their commitment to helping patients with nerve injuries.

At this point, I'd like to open up the line for questions, Jessy?

Operator: Thank you. Ladies and gentlemen, at this time, we will be conducting the question and answer session. If you would like to ask a question, please press star, one on your telephone keypad. The confirmation tone will indicate that your line is in the question queue. You may press star, two if you'd like to remove your question from the queue. For participants using speaker equipment, it may be necessary to pick up your handset before pressing the star keys.

Our first question is coming from the line of Dave Turkaly with JMP Securities. Please proceed with your question.

Mr. Dave Turkaly: Thanks and, uh, congrats on keeping the momentum going. I guess one quick one - the 5,100 accounts, I don't think I've seen in the past, so I was just curious as to where that number--where that came from, and, uh--I think it's a larger number than I've ever considered. So, any color on that would be great?

Ms. Karen Zaderej: Sure. Hi, Dave. Um, so it is a new number. We've not put it out there before, but we've spent quite a bit of time looking at the targets and potential in the marketplace. So, not only have we looked at 5,100 accounts, uh, but we've also graded those accounts. Uh, so we're not saying that we're going after 5,100 as a high potential account. That's just the universe ranging from, uh, Level 1, Level 2 trauma centers, children hospitals, military hospitals, all the way down to, uh, surgery centers that would do surgery related to nerves.

And so, what we want to really showcase is that the universe is 5,100. Uh, having said that, we're in only 374 of those accounts as active account. Uh, so we're really just scratching the surface. And even the 374 accounts that we're in, uh, we still are typically at one surgeon, uh, and even a part of that surgeon's treatment algorithm. So, we've got a lot of growth opportunity.

Mr. Dave Turkaly: Great. And on the 374--thanks for the detail. Um, you know, you mentioned that there's five times more revs that they use all three products. Just directionally, I mean, how many accounts are doing this today? Is it 50 or--any color around what the, you know, the number of accounts that use all three is?

Ms. Karen Zaderej: Yeah, I don't have that level of detail to provide today. But, that is interesting that that five times revenue has been a very consistent number for us. As we look back over time, as we get accounts up to that level where they have three products, um, we've remained very consistent and demonstrating that that brings us up to a, uh, again, a five time increase in revenue. And, uh, and I've always use that as a proxy for really adoption towards their treatment algorithm, that it's mathematically more than just that they use three products. It’s that they’re really starting to adopt the best practices when they do that.

Mr. Dave Turkaly: And last quick one maybe for Pete here - um, guidance for above 80 on the gross margin line. Could you just help us think about, you know, the 85 this quarter and what factors to consider that would kind of make that not be the norm if we’re looking at sort of sequential sales increases? Thanks a lot.

Mr. Peter Mariani: Yeah, uh, thanks, Dave. You know, we’re just, uh--we’re happy with the gross margin that we were able to, uh, provide in the quarter. Uh, we’re comfortable that, uh, the business is operating well, and we just think that, uh, providing guidance on gross margins above 80 percent is the conservative place for us to be, um, and we’ll continue to be there. But, uh, we--the company is performing well here, and we, uh, we think we could continue to do above 80 percent margins.

Mr. Dave Turkaly: Well, it’s an impressive number. Thank you.

Mr. Peter Mariani: Yeah.

Ms. Karen Zaderej: Thanks, Dave.

Operator: Thank you. And as a reminder, if you'd like to ask a question, please press star, one on your telephone keypad at this time.

Our next question is coming from the line of Bruce Jackson with Lake Street Capital Markets. Please proceed with your question.

Mr. Bruce Jackson: Hi, guys, nice quarter.

Mr. Peter Mariani: Thanks.

Ms. Karen Zaderej: Thanks, Bruce.

Mr. Bruce Jackson: Um, okay, so first with the, uh, price increase, can you give us a, uh, general sense of, um, what percentage that was?

Ms. Karen Zaderej: Well, so our price increase, we took on March 1st, uh, and as we have done in the past, and it varies by item code. Um, so there's not one number across the board. But, we've netted out between price and mix still in the sort of high single-digits, um, about frankly where we've been in the last several years, as well.

Mr. Bruce Jackson: Okay, great. Um, second question - um, sometimes the, uh, the, uh, demand can be somewhat, um, lumpy, for lack of a better term, because you've got seasonality and various other, um, end-user patterns. Um, how would you character the sales, um, coming out of the quarter and going into July? Is it like, uh--would you say that demand is, um, steady, up a little, down a little? How would you, um, say we're heading into the third quarter here?

Ms. Karen Zaderej: Well, we've talked, um, that especially the trauma market, the incidence of trauma follows activity. And so, certainly, locally, there can be shifts where we see Mayo Clinic has a high seasonality in spring and fall because they tend to refer from an agricultural, uh, referral network or referral area, um, whereas Vail will be, uh, winters and summer because they have the timber industry and they have the sporting events around, uh, snow.

And so, there's certainly some differences locally, but we believe that the seasonality is higher in, uh, in the summer months, and so that we see an impact historically in second and third quarter. Um, we don't give quarterly guidance, so I don't have anything I can tell you forward looking into third quarter and fourth quarter of this year. But, if I look back historically, you've seen that there's been a, um, a higher growth in second and third quarter.

Mr. Bruce Jackson: Okay. I mean, that's helpful. Then, um, the last question - the, um, the sales force, um, productivity looked really good this quarter. You've got the reps who are now annualized, and they're, um, they're, um, up to full speed. And we've had some discussions in the past about the model where you don't necessarily have to have the reps in the operating rooms to do all the procedures. Um, I'm just curious to get your latest thinking on where the, um, the sales per rep could get to?

Ms. Karen Zaderej: Well, as we've modeled this, um, we've modeled it not as much on our own history, obviously, as it is on other similar, uh, markets with a similar selling process. So, again, this is not a service model. It's a model where the reps come in to help, uh, convert a surgeon and to get them comfortable with the change. So, they're gonna be in the first say six to ten cases with the surgeon, and then they're gonna come back as the surgeon is changing the treatment algorithm, but not for the same types of cases over-and-over again.

Uh, if I look at other, uh, other products that have had that similar selling process, they've been on average about $2 million per rep. That's what we think, uh, will be a reasonable number for us to get to on average. Um, you know, again, as you can see from our numbers, our reps are not on average at 2 million yet, but that's also because they're in the learning stages. So, that's what we're working towards.

Mr. Bruce Jackson: Okay, um, great. Again nice quarter. Thank you very much.

Ms. Karen Zaderej: Thank you.

Mr. Peter Mariani: Thank you.

Operator: Thank you. It appears we have no additional questions at this time, so I'd like to pass the floor back over to management for any additional concluding comments.

Ms. Karen Zaderej: Well, thank you, Jessy.

And I want to thank everyone for joining us on today call. Uh, we look forward to speaking with you on the Q3 conference call in November.

Operator: Thank you. Ladies and gentlemen, this does conclude today's teleconference. Again, we thank you for your participation, and you may disconnect your lines at this time.