Second Quarter 2015 Earnings Conference August-06-2015 Confirmation # 13614298 Page 1

## AXOGEN Second Quarter 2015 Earnings Conference August-06-2015 Confirmation # 13614298

Operator: Greetings, and welcome to the AxoGen Second Quarter 2015 Results Conference Call. At this time, the participants are in 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.

I would now like to turn the conference over to Mr. Michael Polyviou, Investor Relations. Please go ahead, sir.

August-06-2015

Confirmation # 13614298

Page 2

Mr. Michael Polyviou: Thanks, Jerry, and good afternoon, everyone. Uh, thank you for joining

us today for the AxoGen, Inc. conference call to discuss the financial results for the second

quarter ended June 30, 2015.

Today's call is being broadcast live via webcast, which is available on the AxoGen website.

Within an hour following the end of today's live call, a replay will be available on the company's

website at www.axogeninc.com, under Investors.

Before we get started, I would like to remind you that during the course of this conference call,

the company will make projections and forward-looking statements regarding future events.

We encourage you to review the company's past and future filings with the SEC, including,

without limitation, on 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 product development, product potential, regulatory environment, sales and

marketing strategies, capital resources or operating performance.

And with that, I would like to turn the call over to Karen Zaderej, President and CEO of AxoGen.

Karen?

August-06-2015

Confirmation # 13614298

Page 3

Ms. Karen Zaderej: Thank you, Michael, and good afternoon, everyone, and welcome to

AxoGen's Second Quarter 2015 Conference Call.

Joining me on the call today is Greg Freitag, who many of you know as our general counsel and

senior vice president of business development. Greg is also a director of the company and,

until April of 2014, served as our chief financial officer.

Effective today, Bob Johnston was terminated as CFO and Greg has reassumed the chief

financial officer's responsibilities at AxoGen.

We are very pleased that Greg provides a seamless transition and he'll be joining me next week

as we meet with investors at the Wedbush Conference in New York City. Today, he'll review

the financial highlights of the quarter.

Our record performance in the second quarter of 2015 demonstrates AxoGen's growing

momentum. Our strategy, which is aimed at elevating the levels of awareness and usage of our

portfolio of nerve repair products is succeeding.

August-06-2015

Confirmation # 13614298

Page 4

Our professional education forums and sales team performance are driving increased customer

interest for our peripheral nerve injury solutions. Our execution enabled us to generate record

revenue of 6.4 million, an increase of 52 percent from the prior year quarter. In addition to

reporting record revenue, our gross margin also reached a record level of 83.8 percent.

The peripheral nerve repair market in the US is large. And in the clinical areas in which we

operate, it is estimated to be more than 1.6 billion. Our off-the-shelf products address all of the

surgeon's nerve repair and protection needs and avoid unnecessary complications and costs

derived from an additional surgery to harvest autograph tissue.

The first of these products is Avance Nerve Graft. It is donated human nerve tissue processed

through our proprietary cleansing and deceleration methods and intended for the surgical

repair of peripheral nerve gaps.

Next is AxoGuard Nerve Connector, the only extracellular matrix coaptation aid for the

tensionless repair of severed peripheral nerves.

And finally, AxoGuard Nerve Protector, the only extracellular matrix surgical implant used to

protect injured nerves and to reinforce the nerve reconstruction while preventing soft tissue

attachments.

August-06-2015

Confirmation # 13614298

Page 5

More than 900,000 nerve injuries will be surgically repaired this year in the United States alone.

AxoGen's portfolio of products provides surgeons with an off-the-shelf solution for the repair of

a vast range of peripheral nerve injuries. AxoGen products offer a less invasive option to

patients by eliminating the need for additional surgeries associated with the harvest of

autograph tissue, which may cause a loss of function in the impacted area.

Eliminating the need for an additional surgery also provides healthcare economic value by

reducing risk and cost of these procedures. These new repair pathways for nerve injuries

provide a win-win-win for the patients, surgeons, and hospitals.

The harvest of the autograph is not separately reimbursed and there is no financial driver for a

hospital to perform this procedure. Elimination of the procedure to harvest the patient's own

nerve tissue will save 30 to 90 minutes in total procedure time. That, in turn, reduces the cost

of both OR time and anesthesia.

Using a national average for OR cost, this time savings equals between \$3,200 and \$9,500 in

cost savings for the hospital. In fact, not only does the reduction in time save OR and

anesthesia cost, it presents a typical large hospital with the opportunity to gain the equivalent

August-06-2015

Confirmation # 13614298

Page 6

of as much as six to nine days of additional OR time to perform more surgical procedures in a

year.

In addition, eliminating the need to harvest the patient's own tissue by use of an off-the-shelf

AxoGen nerve repair product, may allow for the use of local or regional anesthesia instead of

general anesthesia, which further reduces cost.

AxoGen's off-the-shelf nerve repair products may also help reduce costs associated with

complications that may arise from nerve autograph harvest procedures, particularly, surgical

site infections, one of the most common complications of any surgical procedure. The

treatment of a surgical site infection cost an average of over \$20,000 and can exceed over

\$100,000.

Hospitals are increasingly being held accountable for readmissions, avoidable complications,

and serious reportable events that occur during a patient's time in the hospital. By eliminating

the need for an additional surgery, AxoGen's products reduce the chance of a hospital acquired

infection.

Now, let's turn to our execution strategy and highlight how the team is successfully executing

our plan, what I like to refer to as our four pillars of growth.

August-06-2015

Confirmation # 13614298

Page 7

First, we continue to generate higher levels of market awareness for AxoGen's branded

products. By engaging with surgeons at hospitals, clinical conferences, promotional events, and

surgeon education courses, we are introducing more and more surgeons to the benefits of our

new nerve repair options.

Also, in a recent series of radio interviews, we engaged with our key constituents to highlight

how our products have helped military personnel with nerve injuries, the promising ability of

nerve repair to restore erectile function after non-nerve sparing radical prostatectomy, and the

opportunity to repair the nerves responsible for sensation in the mouth following complications

during wisdom tooth removal.

The cumulative effect of these efforts is shifting the conversations with surgeons. They are no

longer focused on just the basic science of our products or the more the practical aspects of

using our products.

Our second pillar of growth is focused on surgeon education and the development of surgeon

advocates on best practices and nerve repair to help drive awareness of surgical techniques

that lead to positive outcomes.

August-06-2015

Confirmation # 13614298

Page 8

So far in the first half of 2015, we've conducted four best practices and nerve repair educational

events with the total attendance of over 100 surgeons. We also hosted our first international

event in Milan, Italy just prior to the 20th Congress of the Federation of European Societies for

Surgery of the Hand, or FESSH. This program, titled Advances and Best Practices in Upper

Extremity Nerve Repair, was led by a faculty of internationally known surgeons from both the

US and Europe and attendance exceeded 60 international surgeons. These professional

education forums are highly successful and the return on investment is significant as we've

seen an increase in revenue of approximately 60 percent from surgeons who've attended our

two day courses.

For example, the revenue generated from the first four upper extremity events held in late

2013 and early 2014 have demonstrated over a half a million dollar increase in the 12 months

following each course.

The third pillar of our growth strategy is to grow the body of clinical evidence to support the

use and benefits of our products. We enrolled the first subject in the recon study to support an

investigational new drug application for Avance Nerve Graft. This phase three clinical trial

compares AxoGen's Avance Nerve Graft to synthetic nerve tubes for bridging gaps in peripheral

nerve tissue and will support the biologic's license application, or BLA, that we are pursuing.

August-06-2015

Confirmation # 13614298

Page 9

Pursuant to an enforcement discretion granted by the FDA, we continue to market Avance

Nerve Graft while it is transitioned to this biologic product.

We believe that it is a competitive differentiator and a further barrier to entry. As we

anticipated, it would take someone starting today at least eight years to get a product

commercially available through the BLA pathway.

In addition, at the FESSH conference, there were three clinical presentations on the use of

Avance Nerve Graft. The first presentation focused on the use of Avance Nerve Graft to repair

long gaps in nerve tissue in the upper extremity and hand. The second presentation compared

outcomes from nerve repairs in the upper extremity using Avance Nerve Graft, synthetic tube

conduits, and autograph nerve tissue.

The third presentation focused on outcomes of digital nerve repairs made with the Avance

Nerve Graft.

Finally, we're pleased that the first peer review clinical paper was published in the Journal of

Hand Surgery on the use of AxoGuard Nerve Protector and the repair of recurrent cubital

tunnel repair. In this study, nerve decompression, combined with AxoGuard Nerve Protector,

August-06-2015

Confirmation # 13614298

Page 10

showed a reduction in post-operative pain and improved grip and pinch strength with an

average of 41 months of follow up.

Our fourth and final growth pillar is sales execution. Our strategy has been centered on

simultaneously increasing the frequency of usage in existing accounts while at the same time,

expanding our sales footprint by adding new accounts.

In Q2, an account that ordered all three of our brands generated five times more revenue than

an account ordering just one brand. So, we continue to drive usage of the full portfolio to

realize this increased penetration.

To achieve our desired goal, we ended the second quarter with 32 direct reps. And as of today,

we have 34 direct reps with a goal to end the year with 35 to 39.

At the end of June, more than half of our direct reps in the US had been with us for more than

12 months.

In addition to our direct sales team, we had 23 territories managed by our independent

distributors and our full team is now more--far more knowledgeable on the best practices of

nerve repair and that is continuing to fuel our growth.

August-06-2015

Confirmation # 13614298

Page 11

I also want to provide an update on processing as we continue to accommodate our growth.

We have entered into a license and services agreement with Community Tissue Center, an

accredited member of the American Association of Tissue Banks and one of the largest non-

profit tissue banks in the United States.

Last year, CTS distributed more than 355,000 tissue grafts to over 5,000 hospitals, physicians,

and surgeons. As a result, we will be moving processing of Avance Nerve Graft from our

current location to CTS's facility in Dayton, Ohio. We will continue to process and package

Avance Nerve Graft using our employees and our equipment located at CTS.

CTS's infrastructure will provide a cost effective, quality controlled, and licensed facility for our

processing.

We anticipated that all processing will be transferred to the CTS facility by the end of 2016 first

quarter.

We're off to a solid start through the first six months of the year. With this progress and

continued momentum, we're raising our revenue guidance and now expect, uh, 2015 full year

August-06-2015

Confirmation # 13614298

Page 12

revenue to exceed 25 million. And we expect to maintain our annual gross margins in the mid

to high 70 percent range.

With that, Greg will provide you with some additional details on our financial results. Greg?

Mr. Greg Freitag: Thanks, Karen. I'll focus my comments on the financial highlights during our

second quarter.

Our revenue increased 52 percent to \$6.4 million compared to last year's second quarter of 4.2

million. The growth was primarily due to increased product usage by existing accounts and the

addition of new customers catalyzed by the additions to our sales force.

Gross profit for the second quarter increased 62 percent to \$5.38 million compared to \$3.33

million for the prior year second quarter. Gross margin was 83.8 percent compared to 78.9

percent in the year ago second quarter.

The year over year expansion reflects processing efficiencies and a favorable product mix. We

continue to enjoy favorable gross margin that could vary throughout the year due to product

mix and other processing factors, including our move to our new facility at CTS.

August-06-2015

Confirmation # 13614298

Page 13

Now, let me turn to expenses.

As we have discussed in prior calls, we continue to invest in the sales and marketing to raise our

awareness and to expand our sales footprint. Sales and marketing expenses increase

approximately 43.4 percent to \$4.8 million compared to last year's second quarter of \$3.4

million due to the expansion of the direct sales force, increased support for both the direct

sales force and independent distributors, and education.

We ended the quarter, as Karen said, with 32 direct reps out from 23 at the end of the 2014

second quarter. We also held two surgeon education forums in this year's second quarter

compared to just one in last year's comparable period. However, with a 52 percent quarterly

revenue increase, sales and marketing expenses as of--as a percentage of revenue declined to

75 percent for the second quarter of 2015 compared to approximately 79.6 percent for the

same quarter in 2014.

For the second quarter of 2015, general and administrative expenses increased 15.7 percent to

1.98 million compared to \$1.71 million in the second quarter of 2014. As a percentage of

revenue, general and administrative expenses continue to decrease on a quarter by quarter

basis due to the significant revenue growth.

August-06-2015

Confirmation # 13614298

Page 14

R&D spending increased 32.4 percent to roughly \$736,000 compared to the year ago second

quarter. Research and development includes AxoGen's product development and clinical

efforts substantially focus on SBL for the Avance Nerve Graft. This activity varies from quarter

to quarter due to the timing of certain products--projects. It is a substantial portion of the

research and development expenses in 2014 and thus far in 2015 relay to expenditures for such

clinical activity, including preparation for and the start of the pivotal clinical trial for the BLA

and hiring additional personal to support both clinical and product development activities.

It is expected that costs associated with the BLA will continue to increase as more patients are

enrolled in the trial over approximately the next two years.

As a percentage of sales, R&D expenses continue to decline as we have continued to show a top

line growth.

The second quarter interest expense was approximately \$1 million compared to approximately

1.4 million in the second quarter of 2014. The decrease was due to the difference in interest

expense related to the Three Peaks facility compared to the interest expense related to the

former PDL royalty contract.

August-06-2015

Confirmation # 13614298

Page 15

We ended the second quarter with 15.62--\$15.6 million in cash. Our monthly cash burn for the

second quarter was approximately \$1.2 million. However, this included extraordinary

payments for expenses related to our first quarter financing and equipment purchases for

expansion in our Burleson distribution facility, representing approximately \$160,000 per month

of that burn.

As we have grown the top line significantly, we have also continued to reduce our net loss. For

the six months ended June 30, 2015, we decreased the net loss over \$1.2 million compared to

the six months ended June 30, 2014.

With that, I will hand the call back over to Karen for closing remarks.

Ms. Karen Zaderej: Thanks, Greg. With the increasing acceptance and adoption of our product

portfolio and the successful execution of our four pillar growth strategy, we're exploring

additional revenue opportunities, which include new geographies and new market applications

for our existing products, which can begin to contribute to our growth during 2016.

Our international business represents less than 6 percent of revenue today, but we see

significant growth opportunities in certain EU and Asia Pacific countries. With a number of

nerve injuries, it's comparable to the US market.

August-06-2015

Confirmation # 13614298

Page 16

We've been focused on building awareness and engaging the international key opinion leaders

as we seek to build champions for our products in these markets. At the same time, we're

pursuing regulatory approvals and partnerships with leading distributors in these international

markets.

With a solid business plan, proven track record, an increasing body of clinical data supporting

the benefits of our products, we expect our international business to be a bigger revenue

contributor in 2016.

I also want to highlight nerves severed during prostate cancer surgery. The cavernous nerves

that control erectile function, incontinence line on the side of the prostate and are sometimes

removed when cancer has spread beyond the prostate. In this situation, high rates of

impotence and incontinence are reported and there is a need to evaluate options to repair the

nerve at the time of surgery.

During the second quarter, we completed a pilot clinical study assessing cavernous nerve

reconstruction with the Avance Nerve Graft following radical prostatectomy.

August-06-2015

Confirmation # 13614298

Page 17

The results of the study demonstrated the technical feasibility and promising ability of this

technique to restore erectile function and reduce incontinence. We are currently examining

the market potential and preliminary strategies for this application for our processed nerve

allograft.

Before taking questions, I want to thank our investors for their continued support and all the

members of the AxoGen team for their commitment in helping patients with nerve injuries.

We're off to a solid start for the second half of 2015.

Operator, we're ready to now to take some questions.

Operator: Thank you. At this time, we'll be conducting a question and answer session. If you

would like to ask a question, please press star, one on your telephone keypad. A confirmation

tone will indicate 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.

One moment, please, while we poll for questions.

August-06-2015

Confirmation # 13614298

Page 18

The first question is from Tao Levy, Wedbush Securities. Please go ahead, sir.

Mr. Tao Levy: Great. Thank you very much. Uh, good afternoon, everyone.

Ms. Karen Zaderej: Hi, Tao.

Mr. Greg Freitag: Hey, Tao.

Ms. Karen Zaderej: How are you?

Mr. Tao Levy: I'm good. Thank you.

Um, so, uh, let's see. In the quarter itself, um, I was wondering if maybe you could give us, um,

you know, some of the, you know, typical breakdowns that you provided in the past. Uh, you

know, uh, uh, Avance versus AxoGuard, um, kind of metrics.

Mr. Greg Freitag: Yeah. So, um, from a product mix standpoint, um, we continue to see what

we see in the market between the two product lines in Avance and AxoGuard. Um, we don't do

a specific breakdown of the AxoGuard product line, but it's starting to get a little bit closer to

August-06-2015

Confirmation # 13614298

Page 19

50-50 breakdown. Um, somewhere, um, around that--the quarter to the six months, you're at

52 to 55 percent range with Avance.

Um, and so, over the last couple of years, that's collapsed at about 5 percent. We used to be at

about 60-40 and it's solidly 55-45, um, in--you know, in that range.

Mr. Tao Levy: And you said--sorry. Um, uh, it's roughly--.

Mr. Greg Freitag: --It's about 50--52 to 54 percent Avance right now. Um, and the reason I say,

depending if you're looking at the three months or the quarter or the six months.

Mr. Tao Levy: Gotcha. Okay. Um, and, uh, is there--you know, think about, you know, that

move down in the percent of revenues. Is that, um--is that surprising? Um, is--you know, do

you expect it to continue moving down as, uh--as surgeons get more comfortable with using,

uh, AxoGuard and just, you know, numbers wise, um, might, uh--there might be more

procedures that they're accustomed to using, uh, tissue products in?

Ms. Karen Zaderej: So, first, just to be clear, all of our products are increasing in revenue and

units. But in terms of mix, the mix has shifted to be actually closer to what we think the market

August-06-2015

Confirmation # 13614298

Page 20

potential is. We were heavier before in Avance and frankly, uh, we're not getting, uh, the usage

of some of the AxoGuard products in applications where they had good applications.

And so, we are now, through our work in driving penetration, picking up that, uh--that

additional revenue in cases.

Mr. Tao Levy: Okay. Very helpful.

And so, you know, now, you--you know, revenues are hitting record type, uh, levels. Can you

provide maybe, um--you know, maybe sort of number of, uh, customers that you have or

surgeons who have done a few cases? Uh, trying to see if eventually we can start thinking of a,

you know, uh, same store sales kind of productivity type number.

Ms. Karen Zaderej: Yeah. We don't have any guidance that we've given on number of

customers and numbers of surgeons. So, I don't have anything I can give you good color

commentary at this point.

Mr. Tao Levy: Okay.

August-06-2015

Confirmation # 13614298

Page 21

And then just, uh, last one, um, you know, obviously, um, you know, termination of the CFO,

um, was that, uh, person know kind of issue, you know, that, you know, can't be discussed or,

you know, any insights there would be, uh--would be helpful. Thanks.

Mr. Greg Freitag: So, as we said, I've assumed, um, the CFO position. Um, the termination did

not relate in any way to any of our financial reporting. Um, and, uh, I'm happy--.

Mr. Tao Levy: --That's enough--.

Mr. Greg Freitag: --To--.

Mr. Tao Levy: --Yeah, that's all I needed--.

Mr. Greg Freitag: --Be acting in support. Yeah.

Mr. Tao Levy: Okay.

Ms. Karen Zaderej: And just to remind everybody that Greg also was our CFO earlier. So, it's an

easy seamless transition for us.

August-06-2015

Confirmation # 13614298

Page 22

Mr. Tao Levy: And I look forward to working with you again.

Mr. Greg Freitag: Same to you.

Mr. Tao Levy: Thanks.

Operator: Next question is from Bruce Jackson, Lake Street Capital Markets. Please go ahead,

sir.

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

Ms. Karen Zaderej: Thank you, Bruce.

Mr. Greg Freitag: Thanks, Bruce.

Mr. Bruce Jackson: So, uh, in terms of the, uh--the, uh, surgeon events, they've been extremely

effective in generating, uh, new demand for the product. Um, how many of these events do

you have scheduled for the second half? And do you have any indications as to the, uh--the

potential attendance?

August-06-2015

Confirmation # 13614298

Page 23

Ms. Karen Zaderej: So, we have, uh, completed four year-to-date or through the first six

months. And we have five scheduled in the second half of the year. Uh, attendance ranges

from 25 to 30 is what we generally target and we've had no problems in filling the events. The

events, uh, in fact, uh, very often get wait listed just, uh, because there is a good demand for

them.

Mr. Bruce Jackson: And so, I was just curious to know if, um--if your next event, is it

overbooked yet? I want to know what's the demand for the next one coming up.

Ms. Karen Zaderej: Um, our next one, actually, does not happen to be overbooked because

we're doing it in the summer during vacation season. We're still getting in our target range, but

that one doesn't happen to be overbooked. But, uh, many of the previous events have been.

Mr. Bruce Jackson: Great. Okay.

Um, and then in terms of the, uh--the CTS transition, are you going to have to build up any, uh,

extra inventory to carry you through?

Mr. Greg Freitag: Yes. So, one of the things with the CTS, um, which is just a great situation for

us again. Um, as we move that from Life Net [sp], um, one of the things we will do is we'll do

August-06-2015

Confirmation # 13614298

Page 24

some, uh, inventory build in front of that just to make sure in that transition, uh, if we're all off

by a little bit in, uh, some of our moments we have, uh, inventory, uh, so we don't have any

glitches.

Um, and we're dealing with that within our cash flow, but that inventory, whatever we build

with the way that we're ramping right now, uh, quite frankly, just gets resold out, uh, next year.

So, there will be a little bit of a shifting and, uh, a little bolas in there of the inventory, um, while

we do this move and, you know, defensively just to make sure. Um, but, uh, as that move

occurs, we are, uh, ahead of our time frames in doing that. Um, and so, we're very excited to

have that signed, be with good partners, and to be in a position where we're all ready, um,

putting the things in place to, uh, have that, uh, transition be very good.

Mr. Bruce Jackson: Okay. And then with the, um--the Avance sales, was it, um--were they

between 52 to 54 percent for the quarter or for the first six months?

Mr. Greg Freitag: So, what we were is for the quarter, we were looking more around the 52

percent range. And for the six months, it was running, uh, more of, like, about a 54 to 55

percent range. Um, and so, that's what I'm saying, there's been that shift. Although, as Karen

said, as we look at it, that has been stepping its way over the years. If one were to go back to

August-06-2015

Confirmation # 13614298

Page 25

the calls in that question, it's always moved a little bit each quarter. Um, but it really is a

function, but we see is the effort, as Karen said, of the AxoGuard promotion because our unit

volume in the Avance product has been wonderful. Um, and it's just we've been able to speed

up what was a little bit of a lag in the AxoGuard side of the equation.

Mr. Bruce Jackson: Okay. Then, uh, last question. I didn't quite catch the distributor number.

Was it 34?

Mr. Greg Freitag: Uh--.

Ms. Karen Zaderej: --Well, uh, it's 23 independent distributors.

Mr. Bruce Jackson: Okay.

Ms. Karen Zaderej: And at the end of the quarter, it was 32 direct reps, but we've now added a

couple people just in the last couple of weeks. So, we're actually at 34 direct reps today.

Mr. Bruce Jackson: Okay. Great. That's it for me. Thank you.

Mr. Greg Freitag: Thanks, Bruce.

August-06-2015

Confirmation # 13614298

Page 26

Operator: As a reminder, if you wish to ask a question, please press star, one on your

telephone keypad. That's star, one.

At this time, there are no further questions. I'd like to turn the conference--we just had

somebody come in with a question. It's a private investor.

Mr. Greg Freitag: Okay, Jerry. We'll take a question.

Operator: Mr. Kipling Thacker.

Mr. Kipling Thacker: Private investor. And I was wondering if you could tell us anything about

the gross margins as you make the transition to community tissue? Do you expect those to, uh,

continue to improve? Do you expect them to go down? Can you give us some insight into

that?

And then secondly, do you have much, uh, validation work that has to be done in making that

transition from, uh, one location to another? Thanks.

August-06-2015

Confirmation # 13614298

Page 27

Mr. Greg Freitag: Great. Thanks, Kip. Um, so, with regards to the margin, uh, yes, we would

expect that, um, will, um, find a little bit margin--of margin pressure as we change those

facilities. Um, just we'll have some, uh, change in some personnel. Um, and so, we expect that.

That's one of the reasons, um, if you know as our guidance and we've been doing extremely

well in what our margins are. Uh, but we're not expecting that to be, uh, you know, huge

amounts of margin hits. Uh, but, we are preparing for some in that transition, then being able

to get back to full efficiency.

Um, so, yes, but we plan for it, we plan for the numbers. Uh--.

Ms. Karen Zaderej: --So, again our guidance will still remain in the mid to high 70s, um, and

we're comfortable with that.

Uh, in terms of the validation, uh, yeah, there's validation. Any time you move equipment, uh,

or you move to a new manufacturing facility, there are a number of validations you need to do

on both the equipment, uh, and the environment. We manufacture, obviously, in, uh, very

tightly controlled clean rooms. Uh, it's pretty straightforward. Uh, so, we've got protocols all

written. We know exactly what we need to do.

August-06-2015

Confirmation # 13614298

Page 28

But, yes, we will need to do that and that's part of the time lag; why it's more than just moving

equipment, uh, and why we expect to be up and running by the end of first quarter, uh, versus

in the next couple of weeks.

Mr. Kipling Thacker: Okay. Thank you.

Ms. Karen Zaderej: Great.

Mr. Greg Freitag: Thanks, Kip.

Operator: Once again, if you wish to ask a question, please press star, one. That's star, one.

We have a question from Clint Hessler [sp]. He's a private investor.

Mr. Clint Hessler: Hi, there. Nice quarter, by the way. Uh, can you hear me?

Ms. Karen Zaderej: Yes.

Mr. Greg Freitag: Yes. Thanks, Clint.

August-06-2015

Confirmation # 13614298

Page 29

Ms. Karen Zaderej: Thank you.

Mr. Clint Hessler: Okay. Uh, wondering how you intend to handle your burn rate with the cash

on hand versus the, uh--the expenditures.

Mr. Greg Freitag: Yeah. So, uh, we continue to, uh, have the cash that we think, uh, we need in

order to continue with our plan. Uh, one of the things in trying to point out is that, uh, there's

the cash burn, obviously, but also the reduction net loss and we continue to reduce the net

loss, which is important. Uh, there's some timing things between quarters and some

extraordinary items with regard to the cash that pop up here and there.

Um, but at this point, um, you know, as we reported, um, at the end of the quarter, um, we had

a strong cash position. Um, continuing on at, um, \$15.6 million in cash as of June 30.

Mr. Clint Hessler: Yeah. At that rate, though, it looks like just over a year and a half, basically, if

you increase sales and stuff like that.

Mr. Greg Freitag: Uh, yeah, we don't give guidance as to what those numbers are. But, that's a

little bit of trying to point out the cap burn versus the extraordinary items versus the continue

reduction and the net loss. Uh, and as we try to keep moving to now a situation where the

August-06-2015

Confirmation # 13614298

Page 30

reduction and net loss starts being a reflection of what we're trying to do because ultimately,

um, right--that's what we have to get is that turned around to a net income. Um, but the cash,

um, as compared, uh, you know, previously the amount of money that we have and the burn

rates we have, um, you know, as we said at the end of the year, that will just be the direct

calculation, but we keep driving sales.

Mr. Clint Hessler: Yeah, that does look good, by the way. I'm not, uh, [unintelligible]. Anyway--

Mr. Greg Freitag: --Yeah--.

Mr. Clint Hessler: --It does look good what you're doing. So, thank you.

Mr. Greg Freitag: No. No, thank you. Um, and we're--.

Ms. Karen Zaderej: --We're really pleased with [unintelligible--].

Mr. Greg Freitag: --Excited and we're--we are--we're excited as to how things are coming along

with regards to the overall, um, you know, P&L of the company.

August-06-2015

Confirmation # 13614298

Page 31

Mr. Clint Hessler: Yep. So am I. Thank you.

Mr. Greg Freitag: Great. Thanks.

Operator: We have a question from Dave Turkaly, JMP Group, LLC. Please go ahead, sir.

Mr. Dave Turkaly: Hey. Thanks, guys. And I apologize. I've been juggling back and forth a bit

and you may have hit this. But, I just wanted to, uh, clarify, you know, you mentioned some of

the European efforts. Did you guys talk at all about sort of, uh, other geographies you might go

to and how soon that could happen?

Ms. Karen Zaderej: Yeah. Uh, so, we, uh, have started to move into some other countries. And

in fact, um, we're showing about 6 percent of our revenue, uh, of our product sales is today

from international markets. Well, that's still small. We see it as a good footprint and starting to

grow.

Um, and our area of focus has been predominately in Europe and Canada, although we are

moving into some, uh, uh, Asia Pac companies--or countries, excuse me, as well.

August-06-2015

Confirmation # 13614298

Page 32

Mr. Greg Freitag: But, one of the things I think that's important to note is that, uh, when you

look at the regulatory landscape, um, of country to country, which is what we have to do, we've

been working very hard for the last two years to do two things. Three things, actually. Um, to

get countries to the regulatory approval for all of our product portfolio; to get distributors in

place, um, who are distributors who match our own thought process as to educational needs of

the sale of the product. And then as the FESSH conference, um, showed, in order to get both

our key, uh, speakers and the information out into those markets, uh, so that we, uh, start

creating those markets with the same information we've had in the US.

So, what we're very excited about as we, uh, come through the rest of 2015 is to have gotten

the core of our regulatory pulled together, to have gotten our distributors in place, and to also

have gotten that information that we need so in 2016, uh, we are moving forward with all of

that put together. But, while basically, uh, starting our OUS sales, we've been able to have

revenue while we've been putting that in place.

So, we're very excited about what 2016 brings for us from an international basis because we're

getting, um--you know, we've got it pulled together. We're ready to roll.

Mr. Dave Turkaly: And that's great. In terms of just color, uh, ASP and some of the

international markets, should we--I mean, could they be similar to they are here? Given what

August-06-2015

Confirmation # 13614298

Page 33

your product is, the biologic nature, uh, uh, uh, I'm just curious if you have any color on sort of

how the ASP looks, uh, Europe or any of the other territories versus what it looks like there.

Ms. Karen Zaderej: Um, it is similar. It is actually similar to the US. It lags a little bit in just the

timing of price increases. But, otherwise, yes, it's similar.

Mr. Dave Turkaly: Congrats. That 1.4 million sequential bump is, uh--is impressive. So, uh, I'm

glad to see you guys have some good momentum going.

Ms. Karen Zaderej: Thank you.

Mr. Greg Freitag: Thanks, Dave.

Ms. Karen Zaderej: We're excited.

Operator: There are no further questions. I'd like to turn the conference back over to Ms.

Karen Zaderej for closing remarks. Please go ahead, ma'am.

Ms. Karen Zaderej: Well, thank you all for joining our call today. We're proud of this record

quarter and we're off to a solid start to the second half of the year. Have a good night.

Second Quarter 2015 Earnings Conference August-06-2015 Confirmation # 13614298 Page 34

Operator: Ladies and gentlemen, the conference is now ended. You may disconnect your telephones. Thank you for calling.