

FINAL TRANSCRIPT

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JAZZ - JAZZ PHARMACEUTICALS INC at LCM Annual Healthcare Conference

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CORPORATE PARTICIPANTS

Bruce Cozadd

Jazz Pharmaceuticals Inc. - CEO

CONFERENCE CALL PARTICIPANTS

Bill Tanner

Lazard Capital - Analyst

PRESENTATION

Bill Tanner - *Lazard Capital - Analyst*

Thanks everybody for coming to our Seventh Annual Healthcare Conference. Hopefully yesterday was productive and valuable and you got some good ideas and hopefully today will be the same. Please let us know how we can improve upon your experience here.

So very pleased to introduce Jazz Pharmaceuticals and specifically Bruce Cozadd, who is the CEO. Clearly it is one of our favorite names. I think it is one of the most exciting names in call it that kind of mid-cap biopharma space, back from the brink I guess.

Probably a year ago we certainly looked at the Company as having a very important product to treat a very serious disease with which the Company has great, it seems, pricing leverage and great operating margins. And so we are very excited about the stock, specifically, and about what the Company is doing, so without any further, Bruce.

Bruce Cozadd - *Jazz Pharmaceuticals Inc. - CEO*

So thank you, Bill, and Fabrice and the rest of the Lazard team for the opportunity to update all of you on progress at Jazz Pharmaceuticals.

So let me start with our disclaimer. I will be making forward-looking statements today. Please see the risk factors in our SEC filings. I will also refer to guidance a number of times today. All of that guidance is given as of our third quarter earnings call on November 4.

So let's start with the mission of the Company. Our Company exists to develop and commercialize drugs that help patients, but also drugs that provide a return to our stockholders. And to us the key in specialty pharmaceuticals is finding opportunities where you can efficiently commercialize a product. That means take it to a targeted group of physicians so that not only can you generate revenues, but you can actually generate bottom-line earnings.

If we look at the Company today our revenue stream guidance for this year is about \$164 million to \$168 million in net sales. Those are sales with a very high gross margin north of 90% and dropping about a third of top-line revenue all the way to the bottom line.

We report adjusted net income, which is net income factoring out a number of non-cash items, so this is sort of our best approximation for a cash income number. If you note where we were through nine months at \$34 million of adjusted net income and look at our guidance for the full year of \$56 million to \$58 million and subtract, you will see that we are coming into our fourth quarter at a run rate north of \$20 million in bottom-line cash income per quarter.

We believe our commercial infrastructure is highly leveragable. We have 100 sales reps in the field calling on a targeted group of physicians. They are very experienced, very motivated and very productive. And we as a management team are committed



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to delivering continuing growth, not only from our existing commercialized products, but also from our pipeline and from corporate development activities.

On our financial profile, in addition to the revenues and bottom line I just mentioned, I will also point out that our margins in general have been improving and we substantially restructured the balance sheet earlier this year, reducing debt from what had been \$120 million as we entered the year to now \$46 million and taking the rate on that debt from 15% down to 5.75%. Additionally, we have substantial NOLs available that should keep the Company from being a significant taxpayer for several years.

So let's start by looking at our primary product, which is Xyrem. Xyrem is sodium oxybate. It is indicated for the treatment of two problematic symptoms of narcolepsy. Those are cataplexy and excessive daytime sleepiness. It is the only product FDA approved to do those two things.

Narcolepsy, for those of you who aren't familiar with it, is a chronic neurological condition caused by the body's inability to regulate sleep/wake cycles normally. It is an orphan condition that is substantially under diagnosed today. Roughly three quarters of narcolepsy patients remain undiagnosed and the average diagnosed narcolepsy patient experienced their first symptoms ten to 15 years before being diagnosed.

Xyrem has been designated as the standard of care by the American Academy of Sleep Medicine and we have very strong intellectual property protection of Xyrem with seven issued patents protecting the product. We did announce our first Paragraph IV certification against Xyrem last month.

Looking at some of the clinical data on Xyrem and narcolepsy, let's look at the two key symptoms. On the left you will see improvement in the Epworth Sleepiness Scale. This is a measurement of excessive daytime sleepiness.

Excessive daytime sleepiness is not just being tired during the day. It is a very pervasive need for sudden sleep, so an irresistible, overwhelming desire to sleep at a moment's notice.

And what you see here on this 24-point scale is the percentage increase you get on two different doses of Xyrem compared to placebo. And what we see here is that Xyrem returns patients closer to a normal range. And I will point out significantly that these include a number of patients who were on stimulant therapy during this trial, so you are seeing benefit on top of stimulants for many patients, so this is clinically meaningful and highly statistically significant.

On the right I show data on cataplexy. Cataplexy is a sudden loss in muscle tone triggered by strong emotion, whether laughter, sadness or otherwise. And what you can see here in our trial is a reduction, a median reduction of cataplexy attacks of up to 69%. That is median. That means there are patients who didn't do as well. There are also patients who eliminated their cataplexy attacks entirely.

Looking at the AE side of Xyrem, the adverse effects, we do see some common CNS related side effects, the most common of which are nausea, dizziness and headache. And we do have a black box warning on Xyrem as well, indicating that it is a CNS depressant. You don't want to use it with other CNS depressants, including alcohol.

This product has been on the market a little more than eight years and yet we are continuing to drive growth of the product. That includes programs to educate physicians, programs to help in better differential diagnosis of narcolepsy.

Our efforts also include a coupon program which we have enhanced recently that helps limit the out-of-pocket cost to patients. About 95% of patients the last time we had data had monthly out-of-pocket costs of less than \$100.



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We also have an nursing program. We distribute Xyrem out of one centralized pharmacy, so we are shipping directly to each patient. We have dedicated staff at that centralized pharmacy who can reach out to patients, particularly to help them successfully initiate therapy.

And here is a slide showing our results with Xyrem. We reported \$97 million in net sales last year. We are projecting about a 45% increase in sales this year to just over \$140 million.

In our most recent quarterly call we announced that volume growth alone of Xyrem was up 8% third quarter 2010 over third quarter 2009. We also announced a price increase of approximately 20% effective November 1st of this year.

Turning to our second product, our second product is Luvox CR, a once daily formulation of an SSRI, fluvoxamine, indicated for the treatment of two severe anxiety disorders. We promote this product for the treatment of Obsessive-Compulsive Disorder. We do have two ANDAs against this product, but we recently announced an ANDA settlement with the first file that would give us exclusivity through 2013.

If we look at Luvox CR sales we see steady growth with a prediction that sales this year will be up about 30% or 40% from last year's sales. So if we combine the sales you will see that in that the third quarter of this year we reported sales at an annual run rate of \$175 million and you see the good growth year-over-year to a projected \$164 million to \$168 million.

So let me turn now to our pipeline. Most of the focus on our pipeline of late has been on JZP-6, which is taking sodium oxybate, the same drug as in Xyrem, but this time for the treatment of fibromyalgia. This is under review at both FDA and EMA. Our partner, UCB in Europe has announced that they expect action on their filing in the first half of 2011.

With respect to the FDA, we did receive a complete response letter last month. In that complete response letter, among other things, FDA talked about the need for additional studies to finding an appropriate patient population and ensuring methods for safe use. We have met with FDA, had an initial meeting with FDA. It is clear to us from that meeting that the work would need to be preapproval, so we don't see a near-term launch of JZP-6 in fibromyalgia. Frankly, we need additional information from FDA to better understand exactly what that clinical work would entail, most likely in fibromyalgia patients with comorbid conditions and taking concomitant meds.

Our task as a management team is to best define what work would be required, what it would cost, how long it would take, probability of success, maybe most important probability that with success we would move to approval because we thought our last clinical trials were very successful, and what we think the commercial return would be. Until we have all the information we need to complete that analysis we won't be in a position to disclose to you how or whether the program will move forward. We hope to be in a position to do that early in 2011.

Behind JZP-6 on our pipeline we are working on several solid oral dosage forms of Xyrem. Xyrem is currently dosed as a liquid twice nightly, once before bedtime and once three to four hours later. We believe we could have improved convenience for patients, meet patient preference and perhaps eliminate the middle of the night dosing, so we think strong rationale for these programs.

We are also working on a program we designate JZP-8. This is the intranasal delivery of clonazepam, a benzodiazepine for the treatment of recurrent acute repetitive seizures.

We believe a strong unmet medical need remains in treatment of patients with ARS. There are limited treatment options available today. These are patients with epilepsy who despite being on an antiepileptic drug continue to suffer from bouts of seizures.

The only outpatient treatment available today is Diastat, which is a rectal gel. Diastat sales are annualizing now at over \$100 million a year. The product use seems to be limited primarily to pediatric patients. As you can see from the pie chart here, most patients are not pediatric, but we find that adolescent and adult patients with ARS are unwilling to tolerate rectal administration



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of a drug by a caregiver, or a family member or a friend, so we see Diastat sales being limited to a very small percentage of the population.

Physicians and caregivers want an alternative. We think this would represent a very convenient and effective product for this condition. We are planning to give an update early next year on our Phase II work and our formulation work.

Okay, so with that let me return to my initial points. The Company is profitable and growing, good top-line growth, very strong gross margins, dropping a lot of that straight through the bottom line with adjusted EPS guidance for this year at \$1.45 to \$1.50, highly leveragable commercial infrastructure with we think a very excellent sales force out selling our two products today, and a commitment to long-term sustained growth through our commercial products on the market today, our pipeline and our corporate development activities.

So with that, let me stop and I would happy to answer any questions.

QUESTIONS AND ANSWERS

Bill Tanner - *Lazard Capital - Analyst*

Thanks, Bruce. Questions for Bruce? I will ask one. Just as it relates to the JZP-6 for fibromyalgia, now I think when we talk to consultants they talk about patients that have really they call them malignant metastatic pain. It is almost like cancer, so people that have very, very advanced fibro, certainly in a bad way. So a priority, is there a reason to think that the meds that they might be on, because it seems like it is going to be more serious than a garden variety fibromyalgia, might suggest that this is not a good thing to pursue?

Bruce Cozadd - *Jazz Pharmaceuticals Inc. - CEO*

Yes, very good question, Bill. You know it is certainly is true that if you look at fibromyalgia patients in the real world today, many of them are using polypharmacy. They are on a number of meds to treat different things, primarily pain, and some of the medications they are on probably would not be medications you would want combined with sodium oxybate.

So the question is, is there a place for sodium oxybate in the treatment of these patients? Certainly what we saw in our clinical trials where we required patients to wash out of all of their other meds, other than acetaminophen, is we saw very strong improvement in multiple symptom domains of fibromyalgia, starting with pain, where we think we saw results that were as good or better than any of the other agents.

And so what we heard from the patients in our clinical trials, the clinical investigators in our clinical trials and, frankly, physicians who have been using sodium oxybate since it has been on the market to treat fibromyalgia patients, is that many of their patients are perfectly willing to discontinue those other meds to get the benefit of Xyrem. So I think we really have a couple paths to explore here. One is in what cases can you safely use Xyrem with another med, and what cases is it important to find out the patients would be willing to and in fact would not use other meds at the same time?

Bill Tanner - *Lazard Capital - Analyst*

Okay.

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Bruce Cozadd - *Jazz Pharmaceuticals Inc. - CEO*

Yes?

Unidentified Audience Member

With respect to JXP-8, what are the features of intranasal clonazepam (inaudible question - microphone inaccessible)?

Bruce Cozadd - *Jazz Pharmaceuticals Inc. - CEO*

Yes, so a couple things. The first is with seizing patients you are looking for a route of administration that works. Oral it doesn't typically work because of risk of aspiration or accessing the oral route.

Rectal is obviously on the market now. Intranasal is another possibility. People have thought about intramuscular injections, again, a little bit hard for untrained nonprofessionals trying to do an intramuscular injection with a seizing patient.

Intranasal route gives you rapid onset. This is essentially local delivery, so when we say intranasal this is not pulmonary delivery, right? This is local delivery, so easy to access for a caregiver, rapid onset of action, good absorption is really what you are looking for, and then you are trying to balance the therapeutic effect, which is interrupting the seizures against problems with super rapid uptake of drug, right? You don't want to knock people out, so can you get that right balance of beneficial impact relatively to a -- yes?

Unidentified Audience Member

So I get the intranasal.

Bruce Cozadd - *Jazz Pharmaceuticals Inc. - CEO*

Right.

Unidentified Audience Member

What is special about clonazepam for nasal (inaudible question - microphone inaccessible) potentially driven by the same route?

Bruce Cozadd - *Jazz Pharmaceuticals Inc. - CEO*

Yes. So we haven't published these results, but we did some important early pharmacology research where we looked at the question I just talked about, sort of the beneficial versus unwanted effects of rapid intranasal absorption of different benzos, and we were looking for the one that gave us, in our opinion, the right balance and that is why we chose clonazepam.

Bill Tanner - *Lazard Capital - Analyst*

Scott?

Bruce Cozadd - *Jazz Pharmaceuticals Inc. - CEO*

Yes, sir.

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Unidentified Audience Member

(inaudible question - microphone inaccessible)

Bruce Cozadd - *Jazz Pharmaceuticals Inc. - CEO*

Yes. So on the Paragraph IV certification against Xyrem, as I mentioned on the slide, we have seven patents covering the product, five of which are Orange Book listed. Those patents go out to 2019 through 2024 and we believe offer substantial protection.

A number of those patents relate to our restricted distribution system. The restricted distribution system that goes along with Xyrem to help prevent abuse and diversion of the drug was a requirement to get FDA approval of the drug in the first place.

We have a patent that we believe covers that distribution system. It is hard for us to understand how somebody else could get approval without infringing our IP and launch the product. And in particular, since one of the goals of this REMs is to ensure that no single patient is receiving multiple prescriptions of sodium oxybate, it is hard to imagine that another company without access to our database could ensure in fact that they were not shipping drug to a patient who was also receiving Jazz Pharmaceutical Xyrem.

At the August 20th advisory committee meeting for our fibromyalgia NDA, the FDA expressed great concern about our proposal to have side-by-side REMS for narcolepsy and fibromyalgia, even though we would be doing so within the umbrella of one company sharing data across those two REMS. And FDA said even that, in their mind, left too much risk of medication error, so it is hard for me to imagine that a second separate company without access to our database would be able to achieve that.

Unidentified Audience Member

(inaudible question - microphone inaccessible)

Bruce Cozadd - *Jazz Pharmaceuticals Inc. - CEO*

2024.

Unidentified Audience Member

And then (inaudible question - microphone inaccessible)?

Bruce Cozadd - *Jazz Pharmaceuticals Inc. - CEO*

So as part of our restricted distribution system we have physicians register with us. That is to enable them to write a controlled substance. We have a Schedule III product in Xyrem -- and to make sure that they understand the safe use of Xyrem, they understand the AE information, they understand the box warning.

They, through that education, also commit to educate patients about the same thing. Once they have been successfully registered in our system, when they want to prescribe Xyrem to a patient they fax that prescription form directly into our central pharmacy. Our central pharmacy then reaches out directly to the patient to verify information, go over again the safety information and make sure that they are in fact shipping drug to a legitimate patient.



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So in our database we have lots of information about, lots of identifying information on those patients, so we can make sure we know who they are and that they are not getting multiple prescriptions, and lots of information that allows us to track their usage of the drug to see if they are early requesting additional prescriptions, gee, I've run out, gee, I lost my prescription, I need more, which could be signs of somebody that is trying to abuse the drug or divert the drug. Yes?

Unidentified Audience Member

Could you talk a little bit about (inaudible question - microphone inaccessible)?

Bruce Cozadd - *Jazz Pharmaceuticals Inc. - CEO*

Sure. So the question was what audiences do we call on specifically. Our primary audience for the treatment of narcolepsy patients is neurologists, sleep doctors, sometimes including pulmonologists that work in sleep centers and some psychiatrists. And then our audience for the OCD product, Luvox CR is those psychiatrists. Yes?

Unidentified Audience Member

(inaudible question - microphone inaccessible)

Bruce Cozadd - *Jazz Pharmaceuticals Inc. - CEO*

Yes. So the question was persistence of therapy and middle of the night dosing. On persistence of therapy, this is a chronic condition. The product has been shown to maintain its effect in chronic use. It has also been shown that withdrawal of the drug produces a return to baseline of the symptoms, so taking the drug on a chronic basis is required to adequately narcolepsy and we see pretty good persistence.

Like any drug, persistence is not 100%. We get some patients who go off drug early on because they are either not getting the benefit they want or they can't tolerate the AEs. We are always hopeful they will try it long enough to titrate up to an effective dose. Starting dose is 4.5 grams a night. Effective dose is more in the 6.0 to 9.0 gram range, so that is persistence.

On the middle of the night dosing the drug has a very short half-life, less than hour, which is why you need to take it twice a night. And while that sounds counterintuitive to ask people to wake up to take a second dose of the drug, when you are treating an underlying sleep disorder the fact is these patients are often waking up 18 to 20 times a night without therapy. For them, waking up once a night is a blessing.

So I think I have time for one more question.

Bill Tanner - *Lazard Capital - Analyst*

One more question, might ask one. Just on the pricing, I know that on your third quarter call Bob mentioned that the contemplation that you could double the price from here, and I think that is a little mind bending, perhaps for some investors, unless there is a concession that the price at the outset was really too low. And I think we are calculating about a 12% per quarter [K] or 12% per quarter compounded growth rate. How do you view the JZP-6 for the fibro indication, or do you view it not as being a potential anchor on your ability to keep raising prices?

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Bruce Cozadd - *Jazz Pharmaceuticals Inc. - CEO*

Sure. So there were a couple questions buried in there. Specifically, Bob's comment on the call was at double the current price we still wouldn't be a high-priced orphan product, which is a little different from we are going to double the price, just so people hear that.

We do think we have substantial pricing power still in the product. It is a unique product. There is nothing else that does what it does. There is no substitute. It treats a serious condition and it treats an orphan population. In any one health plan there aren't that many Xyrem patients. Remember, we have 8,000 to 9,000 total patients on therapy right now.

And the second part of Bill's question is what are the implications if you move into the fibromyalgia market. Clearly, Xyrem is already priced at a substantial premium to the fibro approved agents, so Lyrica, Savella and Cymbalta, but I think you can hear from the recent discussion at FDA that were we to bring this to market in fibromyalgia it would probably be used behind those other agents, meaning for patients who weren't being adequately treated through other agents, meaning that we really offer a different therapeutic benefit, in which case I am not sure there is a direct comparison between the cost of our therapy and the cost of those therapies.

Bill Tanner - *Lazard Capital - Analyst*

Great, all right.

Bruce Cozadd - *Jazz Pharmaceuticals Inc. - CEO*

I'll stop there. Thank you all.

Bill Tanner - *Lazard Capital - Analyst*

Great. Thanks very much.

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