JAZZ PHARMACEUTICALS INC
Form 425
December 01, 2011
Filing under Rule 425 under the Securities Act

of 1933 and deemed filed under Rule 14a-6 of

the Securities Exchange Act of 1934

Filing by: Jazz Pharmaceuticals, Inc.

Subject Company: Jazz Pharmaceuticals, Inc.

SEC File No. of Jazz Pharmaceuticals, Inc.:

001-33500

Registration No. 333-177528

The following transcript of an investor presentation by Jazz Pharmaceuticals, Inc. (Jazz Pharmaceuticals) on Wednesday, November 30, 2011 contains forward-looking statements, including, but not limited to, related to Jazz Pharmaceuticals growth potential and future financial performance, including 2011 financial guidance, and statements related to the anticipated consummation of the business combination transaction between Jazz Pharmaceuticals and Azur Pharma Public Limited Company (formerly Azur Pharma Limited, Azur Pharma) and the timing thereof. These forward-looking statements are based on Jazz Pharmaceuticals current expectations and inherently involve significant risks and uncertainties. Jazz Pharmaceuticals actual results and the 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, risks related to: Jazz Pharmaceuticals dependence on sales of Xyrem® and its ability to increase sales of its Xyrem and Luvox CR® products; competition, including potential generic competition; Jazz Pharmaceuticals dependence on single source suppliers and manufacturers; the ability of Jazz Pharmaceuticals to protect its intellectual property and defend its patents; regulatory obligations and oversight; Jazz Pharmaceuticals cash flow; Jazz Pharmaceuticals ability to complete the transaction with Azur Pharma on the proposed terms and schedule; and those risks detailed from time-to-time under the caption Risk Factors and elsewhere in Jazz Pharmaceuticals Securities and Exchange Commission (SEC) filings and reports, including in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2011 and definitive proxy statement related to the Azur Pharma transaction, in each case filed with the SEC. Jazz Pharmaceuticals undertakes no duty or obligation to update any forward-looking statements contained in this transcript as a result of new information, future events or changes in its expectations.

Additional Information and Where to Find It

In connection with the proposed transaction, Jazz Pharmaceuticals and Azur Pharma have filed documents with the SEC, including the filing by Jazz Pharmaceuticals of a definitive proxy statement/prospectus relating to the proposed transaction and the related matters, and the filing by Azur Pharma of a registration statement on Form S-4 that includes the proxy statement/prospectus relating to the proposed transaction and the related matters. The definitive proxy statement/prospectus has been mailed to Jazz Pharmaceuticals stockholders in connection with the proposed transaction. INVESTORS AND SECURITY HOLDERS ARE URGED TO READ THE REGISTRATION STATEMENT ON FORM S-4 AND THE RELATED DEFINITIVE PROXY STATEMENT/PROSPECTUS BECAUSE THEY CONTAIN IMPORTANT INFORMATION ABOUT JAZZ PHARMACEUTICALS, AZUR PHARMA, THE PROPOSED TRANSACTION AND THE RELATED MATTERS. Investors and security holders may obtain free copies of these documents and other related documents filed with the

SEC at the SEC s web site at www.sec.gov, by directing a request to Jazz Pharmaceuticals Investor Relations department at Jazz Pharmaceuticals, Inc., Attention: Investor Relations, 3180 Porter Drive, Palo Alto, California 94304, or to Jazz Pharmaceuticals Investor Relations department at 650-496-2800 or by email to investorinfo@jazzpharma.com. Investors and security holders may obtain free copies of the documents filed with the SEC on Jazz Pharmaceuticals website at www.jazzpharmaceuticals.com under the heading Investors and then under the heading SEC Filings.

Jazz Pharmaceuticals and its directors and executive officers and Azur Pharma and its directors and executive officers may be deemed participants in the solicitation of proxies from the stockholders of Jazz Pharmaceuticals in connection with the proposed transaction. Information regarding the special interests of these directors and executive officers in the proposed transaction is included in the proxy statement/prospectus described above. Additional information regarding the directors and executive officers of Jazz Pharmaceuticals is also included in Jazz Pharmaceuticals proxy statement for its 2011 Annual Meeting of Stockholders, which was filed with the SEC on April 12, 2011. These documents are available free of charge at the SEC s web site at www.sec.gov and from Investor Relations at Jazz Pharmaceuticals as described above.

This communication does not constitute an offer to sell, or the solicitation of an offer to sell, or the solicitation of an offer to subscribe for or buy, any securities nor shall there be any sale, issuance or transfer of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction.

CORPORATE PARTICIPANTS

Bruce Cozadd

Jazz Pharmaceuticals, Inc. - Chairman & CEO

CONFERENCE CALL PARTICIPANTS

Dave Amsellem

Piper Jaffray - Analyst

PRESENTATION

Dave Amsellem - ***Piper Jaffray - Analyst***

Okay, let s get started. Dave Amsellem from the Specialty Pharma Team at Piper Jaffray. Our next company presentation is Jazz Pharmaceuticals. It s been a very eventful year for the Company with the significant expansion of Xyrem and also the recent acquisition of Azur Pharma, so much to talk about. With us today is Bruce Cozadd, Chairman and CEO. Bruce, thanks for joining us. I ll hand it over to you for a few brief introductory remarks and then we can go right into questions.

Bruce Cozadd - ***Jazz Pharmaceuticals, Inc. - Chairman & CEO***

Hi, David. Thank you, and thank you, everyone, for joining us this morning. I will say I m going to make forward-looking statements during the presentation, so please do see our SEC filings for a listing of risk factors that could affect whether all of those things come to pass.

I ll also point out that we re in the pendency of an announced but not yet closed transaction. On September 19, we announced a transaction with Azur Pharma. That transaction is expected to close in January, but there is a proxy S-4 statement that s been declared effective by the SEC; I would encourage all of you to see that for additional information on that transaction.

So, by way of introductory remarks, I ll just make a few. The first is that the first part of our corporate strategy right now remains optimizing the value of our lead product, Xyrem. Xyrem, or sodium oxybate, is indicated for the treatment of narcolepsy. The two major symptoms of narcolepsy, those are excessive daytime sleepiness and cataplexy. It s the only drug with that indication distributed under our proprietary distribution system, or REMS, called the Xyrem Success Program.

This product, we ve given guidance this year of $230 million to $235 million in revenues. That s up very substantially from prior periods. And we ve seen really good volume growth of Xyrem in 2011. We came into this year with a growth rate, 2010 over 2009, of about 7% on the volume side. We ve seen that tick up to the 11% and 12% range for each of the past three quarters.

For a product that s been on the market nine years, to see an increasing growth rate, I think demonstrates the effectiveness of the number of the commercial initiatives that we ve put in place over the past 12 months, initiatives that we think will continue to pay off in increased growth of this product in this orphan condition of narcolepsy.

The second piece of our strategy is now to add in additional commercial or near-commercial products to build on our commercial infrastructure, and we took a big step toward achieving that objective with the announcement of the Azur transaction in September.

This will take us from two products to 12 products in CNS and women s health. It will take the combined Company to an estimated $475 million in net sales in its first 12 months as a combined entity. We think the products are a good fit, particularly Prialt, which reminds us a lot of Xyrem, when we acquired Xyrem back in 2005. The transaction also will redomicile the Company to Ireland and have advantages to us, I think, in positioning us efficiently for future transactions as well.

The third piece of our strategy is to selectively invest in R&D. We took a major step toward executing on that part of our strategy by adding a new head of R&D in the last few months. Jeff Tobias has just recently joined us. I think he s very focused right now in supporting our

commercial business, but also in evaluating areas where we can make investments in R&D targeted at bringing new products to market that fit with our specialty focus, physician audiences that are concentrated, which will be well addressed through a modestly-sized sales force.

All three of those pieces of our strategy focus on Xyrem, add new commercial products, and selectively invest in R&D are built over a structure of a Company where the management team tries to think like stockholders. We are stockholders, not just through options. We ve invested our own money in the Company.

Kate Falberg, our CFO sitting next to me, recently bought some more stock in the open market. And every time we make an investment, whether that s in growing the Xyrem business, doing a strategy transaction like the Azur transaction, making an R&D investment, we use the same criteria I think a lot of you would use in thinking through how does this build shareholder value, what s this going to do for us in terms of true economics over time? And I think that s a distinguishing characteristic of our Company.

Coming out of the Azur transaction, which, as I said, we expect to close in January, we ll have a very strong balance sheet, a couple hundred million in cash, no debt. We estimate our cash flow on an ongoing basis will be north of $200 million, so positions us, we think, well for continued growth in future transactions. And with that, David, I ll end my introductory remarks and take questions.

QUESTION AND ANSWER

Dave Amsellem - ***Piper Jaffray - Analyst***

Well, I ll start out with a few of my own, but feel free, anyone in the audience, to jump right in. So, first on Xyrem, two bigger picture questions. Number one is how sustainable is the double-digit volume growth that you ve seen? And I know that on past conference calls you ve talked about new initiatives, patient outreach, and additional physicians that you re calling on. But as the growth continues, what sustains that?

Secondly is on price. Obviously, there s been some significant pricing actions and you re getting or do you think you re getting to a point where you are more limited in what you can do on price? Are you starting to get in the cross-hairs of managed care? So, I think as a starting point, those are two very important topics that we think of.

Bruce Cozadd - ***Jazz Pharmaceuticals, Inc. - Chairman & CEO***

Okay. Let me start with the second first, on price. Xyrem s price today varies, obviously, by dose, from 4.5 grams a night up to 9 grams a night. But at the most common dose, it puts us in the low $40,000 per patient year level. Now, that s assuming that someone actually takes full dose every night, 365 days a year.

But when we compare that price to prices for other drugs that also treat orphan conditions that are serious disorders, and narcolepsy certainly is a serious disorder where the drug truly makes a difference for those patients and where there s no substitute, right? Nothing else with the same indication, nothing else with the same mechanism of action. We actually think Xyrem is at the low end of that range of drug pricing.

We ve got excellent reimbursement coverage, about 80% private pay. 70% of our patients have a monthly out-of-pocket cost of $50.00 or less. Our rate of prior authorizations remains fairly low, so we ve got good coverage. Obviously, you can see by our volume growth rate it actually accelerated over time. So we feel very comfortable that the price we have for the product today remains a good value for the payors, and we haven t seen a change in that landscape over the course of the past couple of years.

On the volume side, we came into this year expecting volume growth rate maybe in the high single digits, and we ve done better than that. And to your question, David, what s the opportunity for additional volume growth? We estimate we re penetrating about 18% or 19% of the diagnosed and treated narcolepsy patient population today. We estimate that s about a 50,000-patient pool in the United States, and we think over time that market share certainly ought to go up.

There s really no competition. The other drugs used to treat narcolepsy for the excessive daytime sleepiness part of narcolepsy are stimulants. Those can and are used together with Xyrem, so that s not an either/or, it s an and proposition. Probably 80% to 90% of our patients and the patients in our clinical trials were also on stimulants.

So we do see continued room for volume growth. Will it continue at double-digit rates? It s hard to imagine that would sustain forever, but I think we re in the early stages of the initiatives we rolled out this year; and for now, we see the opportunity for continued solid volume growth.

Dave Amsellem - ***Piper Jaffray - Analyst***

I have a couple of follow-ups to that, first, on the pricing side. You re certainly comfortable, it sounds like, where price is now. I guess the question is if you were to continue to be aggressive on pricing actions and I m not asking you to tell (inaudible) price increase, but what I am asking is if you were to continue to be aggressive, do you think the managed care landscape would change?

Bruce Cozadd - ***Jazz Pharmaceuticals, Inc. - Chairman & CEO***

I don t have a perfect crystal ball any more than anyone else does. I will say that after we do price increases we watch to see what the reaction is. We watch to see what the payor reaction is; we look at what the physician reaction is.

We look at how many patients there are on therapy. Do all patients who need therapy get therapy? Which, I m happy to say, through a number of initiatives we support, including a patient assistance program where we do provide about 10% of product actually free of charge to patients, we think we are ensuring that all patients have access to therapy regardless of ability to pay.

But this is a data-driven decision for us. So we see what actually happens; we make decisions based on the information we then have at hand. And I ll say the landscape around us isn t static either; it s changed over the last couple of years. And so when we ask what s going to happen in 2012, 2013, 2014, let s see what s happening around us as well. But lately, what s been happening around us as well is that existing products have been taking price increases and new product launches have tended to be at prices north of our cost of therapy.

Dave Amsellem - ***Piper Jaffray - Analyst***

Thank you. And then another follow-up, just on the volume side. So I think you said a little bit north of 9,000 patients were on the drug as of the third quarter call, so the penetration, as you said, is pretty low. So, the question here is, obviously, there is some doctors who aren t aware of therapy. So there s that, but can you identify is there still a lot of what I call low-hanging fruit out there in terms of patients who are clear candidates for therapy who are not adequately responding to stimulants? How high could the penetration be over time?

Bruce Cozadd - ***Jazz Pharmaceuticals, Inc. - Chairman & CEO***

Yes, so the number of patients on therapy over time is obviously a function of how many new patients we bring on to therapy, but it s also a function of how many patients leave therapy. And so we re trying to optimize on all dimensions.

We re certainly looking to make sure that we call on all the physicians who are the right targets for us, and this year we did add several hundred new physician targets where we know they re treating narcolepsy, we know they re writing stimulants for narcolepsy, but they hadn t been in our call pattern before.

We re trying to make sure physicians and patients understand the proper use of the product, how to use it safely. It does have a black box warning, and we want to make sure patients understand that as a CNS depressant, you wouldn t want to use this in conjunction with alcohol or other CNS depressants.

So we re trying to do better education on the physician side to bring more patients into the top of the funnel, but then we also want to make sure that if the patient has been prescribed Xyrem by their physician, that they re likely to fill that prescription. We have uniquely good data on that because the prescription itself is faxed directly into a central pharmacy one pharmacy, and we have that information.

So we actually know our prescription fill rate. For a lot of drugs, that s an estimate; you can do surveys and try to guess. We actually know in each case and we ve seen an increasing percentage of patients written a prescription, fill that prescription.

We know that some patients don t fill the prescription because they have fears about this product. They ve heard about its side effects; they ve heard it s a controlled substance; they ve heard it has a bad reputation.

And so if we can provide good information to those patients through their physicians, through nursing outreach from the pharmacy, to make sure they understand what this condition is, why they ve been prescribed this drug and how to use it appropriately, we see that reflected in a higher capture rate of those prescriptions.

And then the last piece is once they start therapy, initiate therapy, do they understand how to titrate up to an efficacious dose, what to expect to in terms of AEs over the first month of therapy so that they can great this chronic condition successfully?

And we ve seen increasing numbers of physicians prescribing the product. We ve seen a higher capture rate of new prescriptions. And now, we ve seen a higher compliance rate and higher persistence rates for patients who have initiated therapy, staying on therapy long-term. All of those things go to increasing that volume of patients on the drug at any point in time.

Dave Amsellem - ***Piper Jaffray - Analyst***

Okay, that s helpful. Any questions from the audience before we move on to other topics?

Unidentified Audience Member

A couple of months ago it was disclosed that some adverse results from Xyrem had not been disclosed properly. Can you just bring us up to date on that?

Bruce Cozadd - ***Jazz Pharmaceuticals, Inc. - Chairman & CEO***

Sure. I m going to repeat the question since you weren t miked. The question was a couple of months ago it was disclosed that there were adverse events in Xyrem that hadn t previously been properly reported and could I give an update on that?

So back in April or May, we became aware through our own efforts that not all AEs had been properly reported from SDS, our specialty pharmacy through Jazz Pharmaceuticals, and therefore, through our drug safety group on to FDA. We notified FDA immediately. We did report those AEs we became aware of. We publicly disclosed that in May as part of our 10-Q, and at this point we think the FDA is fully aware of all of that.

We did get a 483 based on an FDA inspection that started shortly after that. That was given to us in May. That turned into a warning letter issued to us in October of this year by FDA. And I think it s important to point out to everyone here that we take full responsibility for our need to have a robust, timely, accurate AE reporting system. And that includes the activities of our subcontractors, right, of our outsource providers, including SDS.

And we ve been working very closely with SDS since the time we became aware of this to make changes in policies, personnel, training, systems, auditing, really across the board. And following the receipt of the warning letter in October, we did submit what I think was a very thorough response on November 1 detailing all of the actions we ve taken to ensure that our system works the way it ought to work with reliability.

Dave Amsellem - ***Piper Jaffray - Analyst***

What s your sense of when you think the letter could be closed out? And maybe a better way of asking is what are the next steps now that the response is sitting at the FDA?

Bruce Cozadd - ***Jazz Pharmaceuticals, Inc. - Chairman & CEO***

Ultimately, there is a formal close-out process with FDA on warning letters. We ve made our response. We ve offered to meet with district office out in Alameda to walk through any questions they might have on the materials we submitted. That meeting has not happened yet.

As to timing of getting to close-out, it s hard to predict. A lot of our responses to this situation have already happened and can be documented. Some of them will occur over time; for example, putting in place an ongoing auditing program. Obviously, it will take time for us to then perform those audits, measure the improvements in performance.

It s possible the FDA will want to see that play out over time before closing us out, so I don t think the expectation should be that we get to a rapid close-out. I think the FDA is going to want to make sure the system has been fixed and that that fix works over time.

Dave Amsellem - ***Piper Jaffray - Analyst***

And just to be clear, this doesn t impact your ability the shift, it doesn t impact your ability to promote and then, is there any concern that we should have on those fronts?

Bruce Cozadd - ***Jazz Pharmaceuticals, Inc. - Chairman & CEO***

So, no, there s no change to our ability to run our business other than, obviously, we ve substantially upgraded our drug safety capabilities in AE reporting since the spring. But no, it s had no impact. We disclose in our risk factors that FDA and it s in the warning letter, which is a public document, that FDA, if they re not satisfied, can always take additional steps. We re confident, based on our response, that they re not going to need to take any of those additional steps, so we don t forecast any impact on our business. Did you have a question?

Unidentified Audience Member

(inaudible question - microphone inaccessible)

Bruce Cozadd - ***Jazz Pharmaceuticals, Inc. - Chairman & CEO***

Yes. So, CJ, we re very confident that our search, certainly for deaths, is complete. Will the numbers change over time? The numbers change depending on where you re reading, for a couple of reasons. One is what time period is being looked at, so what s the cutoff point?

And second, what s the description of the pool you re looking at? Sometimes you re looking at US only; sometimes you re looking at combining the data from UCB that markets the product in a number of ex-US markets; sometimes we include cases captured from literature, even if we can t identify the patient specifically.

So sometimes there s a slightly different definition, but the numbers haven t actually been moving. They ve been we ve had a good handle on it s just trying to present it however the relevant regulatory body or medical journal, as the case may be, want us to define it.

Dave Amsellem - ***Piper Jaffray - Analyst***

Maybe it would be helpful if you could give us any just an update on the litigation with Roxane. I guess a couple of questions there. Any dates that have been set, (inaudible) anything particular?

And then secondly, what are your general thoughts on ? For those of us I guess who aren t as familiar with the issues, what are you general thoughts on the major barriers here for a generic and why you think your patents around the REMS, the Xyrem Success Program, will hold up?

Bruce Cozadd - ***Jazz Pharmaceuticals, Inc. - Chairman & CEO***

Sure. I think it s important when we talk about the first element of our strategy being to optimize the value of the Xyrem franchise to recognize that we think the franchise does have very long exclusivity. We have nine patents covering the product, seven of which are in the Orange Book. Those patent dates go out to 2024.

Five of the patents are around the restricted distribution system, although there are other patents for formulation and use. The restricted distribution system patents, we think, are particularly important because part of the FDA s approval in sodium oxybate back in 2002 was conditioned on having a very tight distribution system for this controlled substance, in part to ensure that there s not abuse or diversion.

And an integral part of having a system that s effective that way is having one database that uniquely identifies all patients that are prescribed this drug and shipped this drug to make sure that a patient can t get the drug through multiple sources, can t get it through multiple physicians.

We think any generic company Roxane included will have a difficult time setting up their own distribution system that, A, doesn t infringe our intellectual property, and B, would successfully accomplish the goals of this REMS to make sure patients don t get (inaudible) with the prescriptions.

There aren t any key dates, I would say, set yet in the Roxane litigation. This was litigation that commenced in the fourth quarter of last year after they submitted an ANDA. They re the one Paragraph IV filer for Xyrem, but we are very aggressively defending our IP position on this product. We actually had a number of new patents issued last year, so we re continuing to invest in the protection of this franchise.

Dave Amsellem - ***Piper Jaffray - Analyst***

Bruce, you mentioned the difficulty in circumventing the patent. I then want to touch on the issue on validity. Can you walk us through your thoughts on validity here? And I think it s a sort of a general philosophical question, but the FDA, how do you patent something that essentially the FDA required you to do and what is the invention? And obviously, there are other cases of patents around REMS programs, but give me your sense on how you feel about the validity argument.

Bruce Cozadd - ***Jazz Pharmaceuticals, Inc. - Chairman & CEO***

I ve got five seconds left .

Dave Amsellem - ***Piper Jaffray - Analyst***

Actually, you have more than that, so you re .

Bruce Cozadd - ***Jazz Pharmaceuticals, Inc. - Chairman & CEO***

You re in charge?

Dave Amsellem - ***Piper Jaffray - Analyst***

Yes, go ahead. Yes, you re fine.

Bruce Cozadd - ***Jazz Pharmaceuticals, Inc. - Chairman & CEO***

The patents have been issued. And there are multiple patents, so the validity argument on the first step the patents exist, so somebody s going to have to make a compelling argument that that was a mistake.

Can you patent something that FDA required? I think our distribution system is unique. I think there are elements of it that haven t existed in other restricted distribution systems, and uniqueness or innovation is one source of patentability. Doing something different that hasn t been done before in a unique way that serves the purpose.

And in this case, I think the restricted distribution system for sodium oxybate, as we ve constructed it over time, definitely, definitely does that. Beyond that, we d have to get down to each patent and each claim, and we don t have time to do that.

But as I tell people, if you zoom up to a higher level, you didn t have restricted distribution system-related patents years ago because there weren t restricted distribution systems, right? REMS is a fairly recent concept. There are a limited number of the risk MAPs that preceded REMS, and this was one of the first.

And I m not sure you ll see distribution system patents forever because at this point there s prior (inaudible), right? There are some out there that have received patents. So I think there is a window of time for innovation and patentability of restricted distribution systems, and we re fortunate, I think, that Xyrem is the beneficiary of that.

Dave Amsellem - *Piper Jaffray - Analyst*

Okay. Well, we re out of time. Thank you very much (inaudible) in the audience. Thank you, everyone.

DISCLAIMER

Thomson Reuters reserves the right to make changes to documents, content, or other information on this web site without obligation to notify any person of such changes.

In the conference calls upon which Event Transcripts are based, companies may make projections or other forward-looking statements regarding a variety of items. Such forward-looking statements are based upon current expectations and involve risks and uncertainties. Actual results may differ materially from those stated in any forward-looking statement based on a number of important factors and risks, which are more specifically identified in the companies most recent SEC filings. Although the companies mayindicate and believe that the assumptions underlying the forward-looking statements are reasonable, any of the assumptions could prove inaccurate or incorrect and, therefore, there can be no assurance that the results contemplated in the forward-looking statements will be realized.

THE INFORMATION CONTAINED IN EVENT TRANSCRIPTS IS A TEXTUAL REPRESENTATION OF THE APPLICABLE COMPANY S CONFERENCE CALL AND WHILE EFFORTS ARE MADE TO PROVIDE AN ACCURATE TRANSCRIPTION, THERE MAY BE MATERIAL ERRORS, OMISSIONS, OR INACCURACIES IN THE REPORTING OF THE SUBSTANCE OF THE CONFERENCE CALLS. IN NO WAY DOES THOMSON REUTERS OR THE APPLICABLE COMPANY OR THE APPLICABLE COMPANY ASSUME ANY RESPONSIBILITY FOR ANY INVESTMENT OR OTHER DECISIONS MADE BASED UPON THE INFORMATION PROVIDED ON THIS WEB SITE OR IN ANY EVENT TRANSCRIPT. USERS ARE ADVISED TO REVIEW THE APPLICABLE COMPANY S CONFERENCE CALL ITSELF AND THE APPLICABLE COMPANY S SEC FILINGS BEFORE MAKING ANY INVESTMENT OR OTHER DECISIONS.