JAZZ PHARMACEUTICALS INC
Form 425
November 17, 2011

Filing under Rule 425 under the Securities Act of 1933 and deemed filed under Rule 14a-12 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 replaces the previously filed less complete transcript of an investor presentation by Jazz Pharmaceuticals, Inc. (Jazz Pharmaceuticals) on Tuesday, November 15, 2011.

This transcript 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.

Transcript

Jazz Pharmaceuticals, Inc.

Tuesday, November 15, 2011

8:00 a.m. ET

Host

Good Morning. Let s go ahead and get started. Bill Tanner, one of the biopharm analysts here at Lazard Capital Markets. I d like to thank everybody for coming to the 8th Annual Health Care conference. Hopefully, the next couple of days will be very productive and fruitful for you. Let us know if we can enhance your experience. No better way to kick off the conference today than with Jazz Pharmaceuticals. Very pleased to have Bruce Cozadd with us. He s the Chairman and CEO, as well as Russ Cox, the Senior Vice President of Sales and marketing. Bruce, thank you very much for coming.

Bruce Cozadd

Thanks, Bill, and good morning, everyone. So, I m very pleased to have the opportunity to update all of you on the tremendous progress at Jazz Pharmaceuticals in 2011. I m going to spend a little time on our base business and then talk about the Azur transaction that was announced just a few months ago.

We are very excited about the transaction. There was only one downside with the transactions, and that s that Bill Tanner has been restricted since we announced it since he was representing the other side, but we ll be through that in January, Bill.

I will be making forward-looking statements during my talk this morning, including 2011 guidance and comments about the deal, as always, those are subject to risk factors described in our SEC filings. You get a bonus forward-looking statement slide this morning since we re in the middle of an announcement, not completed transaction, I need to remind all of you to review the information in the S4 Registration Statement and the Definitive Proxy and Prospectus, which have been declared effective by the SEC and mailed to Jazz Pharmaceutical stockholders.

So let s get going by talking about the business we re in, which is specialty pharmaceuticals. We are very focused on building shareholder value. We are doing that obviously by addressing the needs of patients, trying to improve patients lives with three-part strategy. The first is to continue focusing on our core product, Xyrem. I ll spend quite a bit of time on Xyrem in this presentation, even post the Azur deal this will remain the bedrock of our strategy. Second, to acquire additional products to add on top of our existing commercial platform, the Azur transaction certainly fits into this category,

but we expect there will be more deals in the future. Third, to add in a layer of focus R&D investment that we believe is critical to growing value in our business and to creating a sustainable enterprise. Along with Russ Cox joining me today, we have in the front row, Jeff Tobias, who recently joined our company as head of R&D.

We re going to do all of this on top of the way we run our company, which is a very disciplined investor-focused management group. We try to think like owners because we are owners. Some of you may have seen our CFO bought another $100,000 dollars worth of stock yesterday in the market. We really mean it when we say we think like stockholders.

So let s start with the current business overview. Xyrem has shown tremendous revenue growth. You can see here our guidance for 2011, which was last updated on November 1st at $230 to $235 million in sales. Particularly gratifying this year has been the volume growth we ve seen in Xyrem, which has had its three highest volume growth rate quarters in the first, second, and third quarter that we ve seen in several years with double digit growth over the prior year in each of those three quarters.

What is Xyrem? Xyrem is a standard of care for the treatment of narcolepsy, specifically addressing two major symptoms of narcolepsy: excessive daytime sleepiness and cataplexy. It s been on the market nine years. We sell it in the United States. Our partner company is Valeant in Canada and UCB in Europe also distributes Xyrem.

We have 110-person specialty sales force. We are very focused on Xyrem, spending about 90% of their time detailing this product. We ve got a patient group that comprises about 9,000 today. We distribute this product under a restricted distribution system. We call it the Xyrem Success Program.

Narcolepsy itself is an orphan condition. While it s thought there are 125,000 to 200,000 Americans suffering from narcolepsy, it s believed that only about 50,000 of those patients have been correctly diagnosed at this point.

The key symptoms are very debilitating. Cataplexy, which is the sudden loss of muscle tone and response to an emotional stimulus, is a devastating problem for patients experiencing it. Excessive daytime sleepiness or the sudden and irresistible urge to sleep during the day is the hallmark symptom of narcolepsy, and it affects 100% of the patients.

On the right-hand side of this slide you see an add we ran that talked about the problem with differential diagnosis in narcolepsy. Patients who present with narcolepsy often take up to five to ten years to be correctly diagnosed. Xyrem does very successfully address these two key symptoms.

On the left-hand side of the slide, you see data with respect to improving excessive daytime sleepiness, in this case measured by the Epworth Sleepiness Scale. You see that over the course of this 8-week trial, a marked reduction in the symptoms as measured by this scale. I should point out that during this trial patients were allowed to continue on stimulant therapy to the extent they were on it, and about 80% of them were. What you are seeing here is an additive benefit above and beyond what you get with stimulant therapy.

On the right-hand side we show reductions in cataplexy attacks. Our patients in this trial had moderate to severe cataplexy with a median of 21 events per week. You can see here that the higher dose of Xyrem patients experienced a 69% reduction in the number of cataplexy attacks per week.

That s the efficacy side. On the AE side, I should point out that the most common AE s associated with Xyrem are CNS-related AE s, nausea, dizziness, and headache. You ll see at the bottom, there is a black box warning for Xyrem. Xyrem is a Central Nervous System depressant. It is very important that it not be used in combination with other CNS depressants, including alcohol, so the product needs to be used carefully.

This is a little awkward transition, but while we are on the topic of AE s, let me just address the warning letter that the company received last month in conjunction with our AE reporting system. We are fully committed to accurate and timely reporting of AE s. We, in fact, ourselves discovered a discrepancy in AE reporting through our central pharmacy back in April. An FDA inspection did result in a Form 483 in May, and we received a warning letter last month.

It s important to point out that we started corrective actions immediately upon finding this issue back in April/May. We have made a number of changes that we believe do insure that we have a robust system in place. We did respond very quickly to the warning letter. We responded on the first of this month. We ve made a number of changes in personnel as well that we believe buttress our system. Since April/May, I will point out that we have a new Chief Medical Officer, a new VP Drug Safety and Pharmacovigilance, and other management changes designed, again, to ensure that we have a very robust system.

When we look at Xyrem, we believe we have significant exclusivity for this product. There are nine patents covering the product, seven of which are listed in the orange book. This includes a number of patents that are specifically related to our restricted distribution system. That Xyrem Success Program I mentioned earlier. Those patents go out through 2024.

We do have one Paragraph IV filer, that s Roxanne. That happened in late 2010. We commenced litigation in the fourth quarter of last year. There s been little progress in that case thus far.

Other things that we think contribute to the exclusivity of Xyrem include manufacturing and distribution. Now Xyrem or sodium oxybate is actually a Schedule 1 substance as a raw material, Schedule 3 as a pharmaceutical product. That is a little bit of a strange thing to have, split scheduling, but it means that there is very strict manufacturing of the product. We have exclusive relationships with everyone in our supply change.

I will point out for those of you that follow the company closely that we have now received final FDA approval as Siegfried as our new API supplier.

When it comes to reimbursement of the product, we have excellent reimbursement with almost 80% of product covered by private pay. You see we have some government pay as well as almost 10% of our prescriptions going out free of charge under patient systems programs.

There is a relatively low rate of prior offs for the product and a relatively low out of pocket costs with over 70% of our patients having a monthly out of pocket cost of less that $50 per month.

We have a number of initiatives targeted at growing our penetration into this narcolepsy population. You can see at the bottom of the slide that 9,000 patients I mentioned earlier represents only 18% penetration of the 50,000 diagnosed narcolepsy patients.

We are doing a number of things that we think have contributed to an increased growth rate and will continue to fuel our growth rate going forward. That includes new physician targets; physicians that we know are prescribing stimulant therapy. We ve added those new target physicians to our call plan just this year, and we are starting to see the early results of that investment.

Second, increased education around the Xyrem Success Program making sure that physicians correctly set expectations with patients as they re first being prescribed Xyrem therapy. Historically, we had up to a 20% discontinuation rate of patients who received a prescription but never in fact filled it.

Third, we ve increased our services directly to patients making sure that patients understand how to initiate therapy, understand how to titrate up on their Xyrem dose between the 4.5 gram starting dose and the therapeutic range, which is generally 6 to 9 grams per night. Most of our patients are at 7.5 grams.

Our second product that we have on the market today is Luvox CR. Luvox is an extended release formulation of fluvoximine, one of the SSRI s, for treating OCD, which is a very severe anxiety disorder. It affects over 2 million American, often underdiagnosed and undertreated. Our product does have a black box warning, like other SSRI s, which I note at the bottom of the slide. It s been growing nicely. It hasn t been the main focus of our company, particularly in 2011, but we do expect that sales this year will come in north of

the $27 million we announced last year. Our current guidance is in the range of $31 million to $33 million.

So if I put all of our guidance together, one of the things that I think you can see on this slide is that we have substantial operating leverage in our business. That is a roughly 50% to 60% growth in our top line results and a more than 120% growth in our bottom line. So you see while we have invested more on the SG&A side in support of some of those initiatives that I talked about earlier designed to grow volume, you see that the growth does largely come through to the bottom line. We are estimating adjusted net income per share in the $3.45 to $3.50 range for 2011. We do provide a reconciliation of adjusted to GAAP in a slide that you can find on our website.

Now, let me spend just a few minutes on the transaction with Azur that we announced on September 19th. We believe this transaction makes sense from a strategic point of view as well as a financial point of view. On the left-hand side, we detail some of the strategic benefits. It s a diversification of our revenue line with ten new products in CNS and women s health. It gives us an increased scale and platform for growth going forward, and the resources to invest both in additional acquisitions as well as that R&D investment I talked about. Importantly, all five of the key managers of Azur have agreed to join our management team. We think that will give us a broader management team.

In terms of the financial side, it is an accretive transaction that s accretive to our fully taxed adjusted earnings per share going forward. We expect the combined company will have revenues north of $475 million in its first 12 months as a combined organization with cash flow north of $200 million. We expect the balance sheet will be strong. We should close the deal with around $250 million in combined cash and no debt. Very importantly, this transaction will lower the combined tax rate of the organization.

Jazz Pharmaceuticals as a standalone entity would have been expecting to start paying taxes at about a 40% combined rate starting sometime in 2012. As a result of this transaction, we expect our longer term blended tax rate to be in the mid-20 s with a transition year in 2012 in the low 30 s.

So a couple of slides on Azur. I mentioned they have ten products. You can see the breakdown here between CNS and women s health and the nice growth they ve achieved, in part through transactions they ve done during this time. We ve given an estimate of $95 million to $100 million in net sales for 2011. They have a relatively small organization, 170 people. 105 of whom are in their three sales forces, a strong medical affairs group, and a relatively small home office staff in Dublin and in the U.S. headquarters, which is Philadelphia. Their pipeline consists of a couple projects aimed at the clozapine franchise and extending that.

Three slides on their products, the first is Prialt. Prialt is an intrathecal synthetic peptide delivered for treatment of severe chronic pain. This is treating pain in patients for whom

intrathecal or pump therapy is warranted. Prialt represents the only non-opioid alternative for these patients. 2010 full-year net sales were about $20 million, although Azur only recorded part of that since they acquired the franchise in May of 2010.

We see a number of characteristics in Prialt that remind us of Xyrem. It requires a high touch sales capability with heavy clinical emphasis. We see a disparity between doctors with a lot of experience with the product who can use in up to 33% of their patients and the broader market where doctors have had less experience where we see an overall market share of less than 3% of IT pumps. That tells us that similar to Xyrem, getting out and doing good education of physicians on how to properly use the product could make a big difference. Like Xyrem, we think there is a great exclusivity story here.

Second is FazaClo. FazaClo is an orally disintegrating tablet formulation of clozapine for the treatment of treatment-resistant schizophrenia. 2010 net sales of $37 million. This is a largely genericized market, although FazaClo has captured about 10% prescription share. Azur launched a couple of higher dosage strengths of FazaClo in 2010 and is in the process of converting the market over from lower dosage strengths to the higher dosage strengths with more than 27% switched as of the third quarter this year.

There are generic filers against FazaClo, three of them, and Azur has settled with the first to file, which is Teva, giving them the right to enter in July of next year for the lower dosage strengths and 2015 for the higher dosage strengths.

I mentioned the additional clozapine lines in development. That includes an oral suspension formulation with an NDA submission expected this year, as well as a once daily formulation that is in Phase II.

Finally, the women s health portion of the business consists of six products with the fastest growing being Elestrin. Elestrin is a topical gel estrogen replacement therapy with patents through 2022. What we see here in the estrogen market is that the fastest growing portion of that market is transdermal therapy. Within transdermals, the fastest growing portion is topical gels and Elestrin appears to be the fastest growing of those. It s a small product, but showing excellent growth at the time.

If we add in to our 2011 estimated revenues, the historic portfolio, you can see what it does for us in terms of providing some balance and diversification. Yet, you can understand why I say that Xyrem will remain the core of our focus moving forward.

Quick update on the transaction itself. I mentioned that the S-4 has been declared effective, and we ve mailed that to our stockholders. We are expecting a shareholder vote on December 12th. As we disclosed in the proxy, we have voting agreements with about 43% of the Jazz Pharmaceutical stockholders, and 99% of the Azur stockholders. We do need to get customary HSR clearance, but we do expect the transaction, which is a

taxable transaction to Jazz stockholders to close in January of 2012. We will still remain NASDAQ traded under the same ticker symbol.

So with that, I ll wrap up by just saying that we think this is an excellent transaction both from a strategic and a financial perspective and particularly as we think about growing the company over a long period of time. It was an excellent transaction to start out with because it positions us well for additional transactions both because of the financial characteristics of the combined company, strong balance sheet, strong cash flow, but also because of the lower tax rate. That could benefit us as we look at additional transactions going forward.

So with that, I ll conclude. I ve left just a few minutes for questions. I ran a little long on my presentation, in part, because I know Bill is not allowed to ask any question, so I ll look to the people here. Thank you.

Questioner

On the clozapine, what s the difference between orally disintegrating and the other (inaudible)

Bruce Cozadd

One of the prime differences is the delivery itself, particularly in some of these schizophrenic patients, many of whom are institutionalized, ensuring that they actually comply with dosing is important. This is a system that if you put it in the mouth, can t be cheeked, can t be hidden. It s going to dissolve and deliver the drug as opposed to patients who might pretend to swallow, but spit it back out later.

Questioner

The volume growth at around 11% (inaudible). How sustainable is that level of growth?

Bruce Cozadd

Russ, you want to take that?

Russ Cox

Sure. We ve gone from about 12%, which you could argue could have been 10% or 11% first quarter, 11%, and the 11% again. I think we are on a pretty good trajectory. Much of that growth has been driven by what we would characterize as improvements that we ve made in patient experience, whether that be compliance, persistency. As Bruce mentioned before, we have a number of new physicians that we are now targeting that are starting to

actually show some benefit. We think it s a combination of not only improving our existing issue strength, but also new patients. We think it s on a good path.

Questioner

Just a question around the warning letter. What else can you tell us about that in terms of details? Also, have you considered bringing distribution in house? What would be the process around that?

Bruce Cozadd

Two questions. The warning letter and bringing distribution in house. On the warning letter, there is not a whole lot more I can say. It is a public document, so everyone can read it word for word if they like. I will say that we did predict at the time we got the 483 in May that a warning letter was likely, somewhat without regard to our response, just given the nature 483 observations themselves, and that s why we started working immediately to make all of those additional improvements to our systems.

In terms of bringing distribution in house, we really have an excellent relationship with Express Scripts, who is distributing the product now. They ve worked very closely with us to make the improvements that we thought were necessary in systems and some of the programs I described are designed to help increase our market share within narcolepsy are being run very much in partnership with SDS. They are our distributor now. I expect they will be. Will we consider making changes to that over time? Of course, we will look at it, but for right now, I think they are doing an excellent job.

Questioner

You referred to unfilled script rate of 20%. Can you just give a sense on how that number has evolved and where you are now?

Russ Cox

Originally, it was somewhere between 23% to 25%, and that s going back about a year and a half now. So now we are at 20% and we think we are actually in a position to move that down from there. The reason being most likely if you look at why patients drop off, they get scared along the way they are not getting correct information.

We put a new program in place where a nurse actually talks to the patients before they go on therapy. We also are implementing a nurse program that changes the conversation with them, so they really can have in depth dialog. Lastly, we now have a patient program. Market research would tell you that one of the things that caused them to go on therapy was actually talking to another patient who was on therapy. That s just being

implemented. So we think that those two things have a meaningful impact. We re at 20% today. We think it will go down from there.

Questioner

Twelve months from now?

Russ Cox

Hard to predict. Although I can say that the nursing program has moved the needle a couple of points already.

Bruce Cozadd

I m afraid we are out of time, so I m not going to be able to take another question. Thank you all for your attention and thanks, Bill, for your invitation.