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JAZZ PHARMACEUTICALS INC

Form 425

November 02, 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 of an investor conference call by Jazz Pharmaceuticals, Inc. (Jazz Pharmaceuticals) on Tuesday, November 1, 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 June 30, 2011 and preliminary 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 release 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 preliminary proxy statement/prospectus relating to the proposed transaction and the matters described above, 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 matters described above. After the registration statement has been declared effective by the SEC, a definitive proxy statement/prospectus will be filed with the SEC by Jazz Pharmaceuticals and 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 PRELIMINARY AND, WHEN IT BECOMES AVAILABLE, DEFINITIVE PROXY STATEMENT/PROSPECTUS BECAUSE THEY CONTAIN OR WILL CONTAIN IMPORTANT INFORMATION ABOUT JAZZ

PHARMACEUTICALS, AZUR PHARMA, THE PROPOSED TRANSACTION AND THE MATTERS DESCRIBED ABOVE. Investors and security holders may obtain free copies of these documents (when they are available) 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.

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Conference Call Transcript

JAZZ - Q3 2011 Jazz Pharmaceuticals Inc Earnings Conference Call

Event Date/Time: Nov 01, 2011 / 08:30PM GMT

1

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PRESENTATION

Operator

Welcome to the Jazz Pharmaceuticals Third Quarter Financial Results Conference Call. Following an introduction from the company, we will open the call to questions. And I'd now like to turn the call over to Ami Knoefler, head of Investor Relations and Corporate Communications at Jazz Pharmaceuticals.

Ami Knoefler - Jazz Pharmaceuticals - IR

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Good afternoon and welcome to our third quarter 2011 financial results and business update conference call. Our results for the third quarter, including updated financial guidance for 2011, were reported in a press release issued earlier today and available on our Company website.

Among other things, the press release includes a reconciliation of GAAP net income to adjusted net income along with the related per-share amounts. With me for today's call are Bruce Cozadd, Chairman and CEO; Kate Falberg, CFO; and Russ Cox, Senior Vice President of Sales and Marketing.

Following some prepared comments, we'll open the call for your questions.

Remarks we make on this call about future expectations, plans and prospects for Jazz Pharmaceuticals constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including statements related to our financial performance and position, growth potential, tax position, guidance, and the anticipated confirmation of our proposed transaction with Azur Pharma and the potential benefits and timing of that transaction.

These forward-looking statements involve numerous risks and uncertainties that could cause our actual results to differ significantly from those projected including, without limitation, risks and uncertainties associated with the timing and completion of the proposed transaction with Azur Pharma, opportunities and plans for the combined company, including uncertainty of the expected financial performance and growth potential as

well as risks related to Jazz Pharmaceuticals business detailed in our SEC filings, including under the heading Risk Factors in our quarterly report on Form 10-Q for the quarter ended June 30, 2011 and the risks relating to the Azur Pharma transaction disclosed under the heading Risk Factors and elsewhere in our preliminary proxy statement relating to the Azur Pharma transaction filed with the SEC on October 26, 2011. Our SEC filings and reports are available through the Investor Relations section on our website. We plan to file our Form 10-Q for the quarter ended September 30, 2011 with the SEC soon.

Please also note that we have filed a preliminary proxy statement and will be filing a definitive proxy statement and Azur Pharma has filed a registration statement with the SEC. We encourage you to read these and the other relevant materials filed by us and Azur Pharma with the SEC because these documents have important information about the proposed transaction.

Now let's turn the call over to Bruce Cozadd, Chairman and CEO for some opening remarks.

Bruce Cozadd - Jazz Pharmaceuticals - Chairman & CEO

Good afternoon, everyone, and thank you for joining our conference call. I am pleased to report our strong quarterly financial results today, which continue to reflect the successful implementation of our plans to grow Xyrem sales.

The past several months have been a busy time at Jazz Pharmaceuticals as we made significant progress across all three of the core elements of our corporate strategy—continuing to grow Xyrem, expanding our product portfolio and establishing a platform for future growth through the Azur Pharma transaction and, most recently, hiring a new head of R&D and Chief Medical Officer to lead the development team to build and deliver a pipeline for sustainable growth.

Our financial results reflect our continued focus on Xyrem growth. Total revenues for the quarter were \$73 million, an increase of 64% over the third quarter of 2010. Adjusted net income of \$44 million was up 157% demonstrating the Company's continued operating leverage. And, as Kate will detail, we are pleased to be updating our full-year guidance to reflect higher expected sales and earnings for the year.

Let me discuss our progress in more detail starting with the outstanding performance of Xyrem, which continues to exceed the expectations we had coming into this year.

We are extremely happy to see sustained double-digit volume growth this quarter, up 11% over the third quarter of 2010. As you know, this builds on several consecutive quarters of strong year-over-year volume growth. Xyrem volume growth continues to be driven by an increased number of patients on active therapy now reaching over 9,000.

The growth in bottle volume and patients on therapy reflects our ongoing commercial focus and targeted investments to increase the number of patients with key symptoms of narcolepsy who benefit from Xyrem therapy and our continued efforts to improve their overall experience with the product.

We are seeing additional improvements in compliance and persistence rates, again reinforcing the importance of our work with physicians and patients to set appropriate expectations about their treatment and provide continued support through our central pharmacy.

We believe a number of initiatives are fueling this volume growth, including the renewed focus of our sales force on Xyrem and continued enhancements to the services we offer through the central pharmacy.

One specific program is the addition of new physician prospect calls, which began earlier this year. As you may recall, through triangulation of new data, we identified several hundred physicians who were treating narcolepsy with stimulants but were not in our call audience. Outreach to these new potential prescribers began in the first half of the year. Some of those physicians have become familiar with Xyrem and are now prescribing it.

Another effort that is showing early results is a change in the interaction with patients as they are initially prescribed therapy. During the quarter, we launched, through the central pharmacy, a nurse welcome call for new patients. Patients have the option to speak with a nurse who will answer questions and address any concerns they may have about their Xyrem prescription before their first shipment.

The initial reaction to this effort suggests it may help to increase the likelihood that patients who have received a Xyrem prescription will fill that prescription. The welcome call enhances our overall patient offering, reflects our commitment to improve a patient's treatment experience and interaction with the Xyrem success program.

Another key area of focus for our Company continues to be working diligently to ensure that we are in compliance across all of our activities. As you know, last month we received a warning letter from FDA relating to matters covered by the Form 483 we received in May. I want to assure all of you that we take our responsibility to ensure accurate and timely adverse event reporting very seriously.

We have responded to the FDA detailing the many concrete steps we have taken over the past six months to address their comments. Since we first learned of the unreported AEs in April, we have been intently focused on making improvements in our systems. We have worked closely with SDS to revive and implement new procedures at both companies, revised our SOPs and reporting systems, enhanced training of personnel, improved our auditing programs, and made personnel changes in order to prevent any similar situations in the future.

We are confident these improvements address the items outlined in the warning letter and ensure that our systems are effective and compliant.

Another significant development for our Company during the past few months was the signing of our agreement to combine with Azur Pharma to create Jazz Pharmaceuticals PLC. As a reminder, the combined company will have a strong balance sheet as well as a portfolio of 12 products in the US. We estimate it will generate \$475 million in revenues and be highly profitable with net cash from operations of at least \$200 million both in its first 12 months.

As we plan for the long-term growth of our Company, this transaction represents a significant step forward. Not only will it diversify our revenue stream and increase cash flows but, importantly, it creates an efficient structure and platform to leverage our existing business and acquire new products.

The past few months have been an exciting time for both of our organizations, as we work toward our anticipated closing of the transaction in the first quarter of 2012. Just last week the joint S-4 registration statement and preliminary proxy statement were filed, and we are on track at both companies with pre-close activities.

We believe this transaction will add significant value to our Company, and we encourage all of our investors to carefully review the available information describing it when the proxy statement and prospectus are mailed.

Finally, I want to publicly welcome Jeff Tobias as our new SVP Research and Development and Chief Medical Officer. Jeff joined the Company just a few weeks ago to take the reins in R&D as we increase our medical and scientific support for Xyrem and refine our longer-term strategy to develop new products.

With over 20 years of experience in the biopharmaceutical industry, across a range of therapeutic areas and treatment modalities, Jeff brings new scientific and medical expertise as well as proven leadership to our organization. He has shown he can work effectively in a dynamic company environment, has been involved in business development, and has a passion for the commercial side of the business with our mission of helping patients in mind.

Now let me turn the call over to Kate.

Kate Falberg - Jazz Pharmaceuticals - CFO

Thanks, Bruce, and good afternoon, everyone. I'll briefly summarize the third quarter numbers, review our updated guidance, and comment on the impact of the proposed combination with Azur Pharma.

Sales in the third quarter increased to a new record of \$72 million from \$44 million in the prior year's third quarter. Bruce commented on Xyrem revenue growth, which reflects the impact of pricing and double-digit volume growth.

I also want to comment briefly on Luvox CR, which achieved sales of \$9.7 million in the quarter, up significantly from the prior year and from the second quarter of this year.

We estimate that approximately \$700,000 of the increase was due to wholesaler inventory restocking and that inventories were at normal levels at quarter-end.

We were pleased to see maintenance of prescription volumes for this product, despite the change in allocation of our sales force's time toward Xyrem, which occurred in July.

Last quarter I mentioned that we expected Luvox CR to come in at the lower end of our guidance range, and today we are confirming that expectation by lowering our guidance slightly.

Combined SG&A and R&D expenses for the quarter were \$33.8 million. This includes approximately \$6 million in costs associated with the Azur Pharma transaction, primarily legal and professional fees. You'll note that our updated full year expense guidance includes total anticipated transaction-related costs of approximately \$10 million to \$11 million.

Our guidance for non-transaction-related expenses is actually reduced somewhat reflecting continued expense discipline.

Aside from the transaction-related expenses, the \$2.5 million sequential increase in SG&A spending reflects higher incentive compensation related to our strong performance, higher sales and marketing expenses aimed at driving sales growth, and increased expenses in our drug safety group.

Turning to the balance sheet, I'll remind you that we paid in full our outstanding debt of \$33 million in July. As mentioned last quarter, we recorded a loss on extinguishment of that debt of \$1.1 million, which included approximately \$800,000 of noncash writeoffs of unamortized debt issuance costs.

We ended the third quarter with \$113 million in cash and investments and no debt.

Now for our updated guidance for 2011. Xyrem sales guidance is increased to \$230 million to \$235 million. Guidance on Luvox CR is updated to \$31 million to \$33 million. This reflects our continued focus on Xyrem and alignment of sales force priorities with that top corporate goal.

Total net sales are now expected to be in the range of \$261 million to \$268 million. Our combined SG&A and R&D expense guidance for the year is updated to a range of \$114 million to \$118 million, including approximately \$10 million to \$11 million in costs associated with the Azur Pharma transaction. Note that approximately \$6 million of this was reported in the third quarter.

Finally, we are updating our guidance for adjusted net income to be in the range of \$160 million to \$163 million and adjusted net income per share to be in the range of \$345 million to \$350 million, a significant increase from last quarter's guidance.

I would also like to make some comments related to the Azur Pharma transaction, as I know many investors are creating their models for 2012 and beyond. We expect to end this year with approximately \$170 million to \$175 million of NOLs available to offset future pre-tax income. As a result, we expect to begin paying some cash taxes in 2012.

Our book tax rate in 2012 will depend on several factors, the largest of which is the accounting treatment of our NOLs, which remain fully reserved on our balance sheet. Without the merger, we would have expected our book tax rate to be approximately 40% to 41%. With the merger, we expect our tax rate to be lower. And, for modeling purposes, we have suggested that investors assume a book tax rate in the low to mid-30s for 2012 and in the mid-20s for 2013 and beyond.

These numbers exclude the impact of dealer-related amortization. We expect to provide updated guidance on the 2012 tax rate on our fourth quarter earnings call in late February when we will have more clarity around the accounting treatment of the NOLs.

The important tax-related points to note are that subject to its closing, the merger is expected to result in a very significant reduction in taxes applicable to the existing combined businesses and, therefore, significantly greater cash flows.

Future products acquired and developed may receive a greater benefit due to Ireland's 12.5% tax rate, and we expect that cash generated in the future will be freely available for use in the US.

Establishing an efficient corporate structure and platform for growth is an important step in our strategy to continue to deliver compelling top and bottom line growth and build shareholder value.

Thanks again for joining our call today, and I'll now ask the operator to open up the call for your questions.

QUESTION AND ANSWER

Operator

(Operator Instructions) Corey Davis, Jefferies.

Corey Davis - Jefferies & Company - Analyst

Kate, while you're on the subject of tax, I'm not sure I caught all of the nuances there. So to be clear, you, one, will be able to use all of your NOLs? Is that correct?

Kate Falberg - Jazz Pharmaceuticals - CFO

Corey, we do expect that we will likely be able to use all the NOLs, and the merger did not disturb the NOLs.

Corey Davis - Jefferies & Company - Analyst

Okay, and so then as you're reporting each quarter of 2012, there will be a departure between a cash tax rate and what I think you called the book tax rate. Is that correct? And, if so, can you explain that a little bit more?

Kate Falberg - Jazz Pharmaceuticals - CFO

Yes, I think that's an important point that you make, Corey. It's quite possible that in 2012, we'll report on our financial statements a higher tax rate than we actually pay. And that difference would be due to usage of the NOLs, which, as I mentioned, we expect to end this year with \$170 million to \$175 million of NOLs.

Corey Davis - Jefferies & Company - Analyst

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So as you calculate your adjusted EPS, is that tax differential going to show up in the adjusted EPS figure?

Kate Falberg - Jazz Pharmaceuticals - CFO

We do not expect to be adjusting the cash taxes when we report adjusted EPS. I think that adjusted EPS will likely reflect the book tax rate. We will make comments to the extent that we can about our use of the NOLs as we go through 2012.

Corey Davis - Jefferies & Company - Analyst

Okay. Then last question on the volume growth that you saw in this quarter, another one in the double digits any reason not to suspect that this is now a sustainable rate of volume growth in the double-digit range?

Bruce Cozadd - Jazz Pharmaceuticals - Chairman & CEO

So, Corey, this is Bruce. Let me start off the answer, then I'm going to hand it over to Russ Cox to continue. You know, I'll say as you think about a long-term product lifecycle, if you plot out the effect of a continued, strong, double-digit growth rate, you get an acceleration of volume,

right? You're sort of compounding that effect, over time. So I don't think we want to say we know that we'll enjoy this kind of volume growth forever. That's a tough thing to do nine years after a product launch. So that's the long-term answer. But let me hand over to Russ to talk about what we're seeing now.

Russ Cox - Jazz Pharmaceuticals - SVP Sales & Marketing

Yes, Corey, most of the growth that we described for the third quarter is coming from areas like improvements in compliance, improvements in persistency or duration of therapy. We are also seeing some of the programs that we are putting in place, like the prospects program, starting to actually pay dividends. While those programs are still very early in terms of their implementation, it's hard to say whether compliance, persistency, can continue to generate that kind of growth.

However, the new prospects programs and other focus on Xyrem, we believe, will be things that, you know, over the long term will continue to pay off. So that is the plan, and we're going to continue to work against that.

Operator

David Amsellem, Piper Jaffray.

David Amsellem - Piper Jaffray - Analyst

Just a couple so I wanted to drill down on the initiatives to drive volume growth from doctors new to Xyrem. I guess the question here is why weren't they prescribing it in the past? Was it lack of awareness or skittishness about the product? Or maybe a combination of both? And can you talk specifically about what you've done to get these doctors to start prescribing the product? Thanks.

Bruce Cozadd - Jazz Pharmaceuticals - Chairman & CEO

Yes, thanks, David. So to be clear, the physicians that we're speaking about as new prospects are, in fact, physicians we were not calling on at all. So we actually went out and purchased the data in patients who are actually physicians who were treating narcolepsy and treating stimulants triangulated that data against our current call pattern and then built out an additional call pattern to make sure that we were targeting those physicians.

So they're new. Having said that, it takes about four to six months to really get a physician comfortable typically with Xyrem. So you're seeing now we're at that timeframe where we're starting to see the benefits of that.

So it's our same story. It's consistent with what we've done historically with other physicians, but it's a new set of physicians that we're calling on.

David Amsellem - Piper Jaffray - Analyst

But I guess the question here is what's getting them over the hump? I mean, they're treating narcoleptics already, so they must know about the drug, I would imagine. So I guess the question is, what is getting these doctors into the fold, if you will?

Bruce Cozadd - Jazz Pharmaceuticals - Chairman & CEO

Yes, I would venture to say that a large percentage of them really knew very little about Xyrem, to begin with. So some of it is really getting them comfortable with what is the titration schedule, how do you set expectations, how do you work through the central pharmacy to become a prescriber? So there is, really, a curve related. It's not anything new that we're doing with them, it's just that we're spending time with a new group of physicians, and they're on the regular curve that we've seen historically with other physicians.

David Amsellem - Piper Jaffray - Analyst

Okay, that's helpful. And then a question on pricing. I mean, any color on how payors have responded to the most recent pricing action? And what does that tell you about your ability to continue to take price aggressively?

Bruce Cozadd - Jazz Pharmaceuticals - Chairman & CEO

Yes, so based on the current price increase that we implemented, we have not seen any change in payor behavior. And so we continue to monitor volume, and we continue to monitor the payor environment.

Operator

Gene Mack, Mizuho.

Gene Mack - Mizuho Securities USA - Analyst

First, a couple on the FDA, why don't I just get that out of the way? Can you talk just a little bit about what the next steps are and how you've responded to FDA? Do they have a certain amount of time to respond back to you of whether or not things were satisfactory and what's the scenario tree there in terms of whether they're satisfied or dissatisfied?

Bruce Cozadd - Jazz Pharmaceuticals - Chairman & CEO

Yes, Gene, good question. There's no defined timeline for FDA to respond to us. You know, we, as I mentioned, have sent in our response, and we will be following up with our local district to see if there's any other information we can provide to be helpful. You know, it's important for everyone listening to realize that while there's now an exchange of information, the changes we've made, of course, are in effect, right? So we're not waiting for a green light to make changes. We've already made many changes that, in our view, enhance our compliance and the certainty of accurate and timely AE reporting, and that's the most important thing to us. But we now also need to make sure FDA is comfortable with how we've set that up, understands what we're doing and why we're doing it; and understands how we're measuring the effectiveness of the measures we've taken to ensure everything is working as we have designed it to.

How long could this take to completely resolve in terms of getting a formal sign-off? It's a little bit hard to predict. Of course, we're putting in place a program that's designed to run effectively over years and includes checks we're going to do on ourselves and other parties we work with, over time. And whether FDA wants to allow time to go by to see that plan is executed well and what the results of that are, we don't know, and that would be a reasonable thing for them to do. And if they were to do that, that could push off formal resolution of this for quite some time. But, in the meantime, we would continue operating the system we've put in place.

Gene Mack - Mizuho Securities USA - Analyst

You said you've made some personnel changes, which sounds pretty you know, sounds a little bit like [I see] some heads roll. Can you just talk a little bit about what level those personnel changes were made and how widespread?

Bruce Cozadd - Jazz Pharmaceuticals - Chairman & CEO

Yes, I certainly didn't use the terminology you did. You know, our job is to make sure we've got all the right resources in place to ensure the effectiveness of our system including the appropriate level of expertise, the appropriate staffing, the appropriate leadership. And, as you know, we have a new Chief Medical Officer. That's something we've been talking about for some time that we had launched a search for a head of R&D.

We also have a new VP of Drug Safety and Pharmacovigilance. And we've put other very talented folks, many of whom were already part of our organization in positions to ensure that we responded aggressively and effectively and successfully to this problem as soon as we learned about it in April.

Gene Mack - Mizuho Securities USA - Analyst

Okay. And then for Kate, the tax rate, the book tax rate that you've provided for guidance purposes. I'm still a little bit confused there. Will that overstate or understate the actual cash tax pay that might be an easier way for, at least me, to understand.

Kate Falberg - Jazz Pharmaceuticals - CFO

Yes, I would expect that, to the extent that there is a difference between the two the book tax rate would be higher than the cash tax rate so overstate taxes.

Gene Mack - Mizuho Securities USA - Analyst

Okay, okay. And then can you talk a little bit also about what if there was any change in the gross-to-net spread during the quarter on Xyrem?

Kate Falberg - Jazz Pharmaceuticals - CFO

No big change. It was consistent.

Gene Mack - Mizuho Securities USA - Analyst

Okay, and then just, finally, Bruce, maybe you can talk a little bit about how you're going to prioritize R&D at this point? You know, what sorts of initiatives might we start to look at in the near term? How do we think about how you're going to go about this now?

Bruce Cozadd - Jazz Pharmaceuticals - Chairman & CEO

Yes, good question, Gene. The way we're looking at R&D is that we would like to invest in programs that we believe could result in near-term marketed products. Where those marketed products would be a good fit with our focus, which is in places where we can call on a specialist group of physicians and efficiently commercialize a product that we believe will make a big difference to patients.

You know, exactly how and when this will roll out will take some time to determine. We've laid out a long-term strategy that includes beginning to make investments in R&D programs, but I don't think you'll see that overnight.

Operator

(Operator Instructions) Difei Yang, Auriga USA.

Difei Yang - Aruga USA - Analyst

The first question is really just related to the housekeeping of Xyrem. What is the current price of Xyrem?

Bruce Cozadd - Jazz Pharmaceuticals - Chairman & CEO

The current price, the bottle price, is \$2,100 to \$4,100 per month based on the dose. And if you were to assume that patients were compliant, and they were taking 100% you would be in that average of about 41K for somebody who is taking 7.5 grams, which is our average dose. As you know, not everybody is 100% compliant.

Difei Yang - Aruga USA - Analyst

Okay, thank you. And the second question is with regards to this mortality rate. We know that because of the under-reported adverse event, so you have revised the mortality rate from a lower number, I wanted to say, maybe 0.2% upwards to a number that is slightly over 0.6%? Do you have conversation with FDA or do you expect to have conversation with the FDA with regards to potential labeling change? Or do you think that is pretty much the end of the discussion on that line?

Bruce Cozadd - Jazz Pharmaceuticals - Chairman & CEO

Well, that is a complex question. There is a lot in there. Let me remind you that the previously unreported all-cause mortality cases were reported into FDA immediately upon us becoming aware of those. So that happened in the second quarter. In terms of a changing rate, I will also remind you that virtually all of those cases were in the period 2003 to 2007 with a handful of cases in each of 2008, 2009, and 2010. So the biggest change in the all-cause mortality rate was really in the older years and, in fact, gave us a pattern of consistent rate, not increasing rate, over the period from the time of the product launch through the current period. That information has also been made publicly available. We put that in a peer review journal article that was published in August and, yes, we have continued to make FDA aware of all of our findings as we continue investigating not only why these AEs were not reported on a timely basis but also what they mean, if anything, from a safety perspective. And we certainly gave our top-line conclusions as soon as we have reached [some] if we didn't see it in the safety signal in the all-cause mortality rate.

Operator

There are no other questions at this time. (Operator Instructions) All right, it looks like no other questions today. I'd like to turn the call back over to management for closing remarks.

Ami Knoefler - Jazz Pharmaceuticals - IR

Thank you all again for joining our conference call today. I'd like to remind you that we will be presenting at two upcoming conferences later this month - the Lazard Capital Markets 8th Annual Health Care Conference and the Piper Jaffray Health Care Conference both in New York. We look forward to seeing those of you who may attend. Thanks and have a great evening.

Operator

Ladies and gentlemen, that concludes today's conference. Thank you for joining us, and you may now disconnect. Everyone have a great week.

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