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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 is a slide presentation relating to the proposed transactions described therein that was made available beginning on December 7, 2011.

Investor Relations

December 7, 2011

Jazz Pharmaceuticals
Innovation that performs

Forward-Looking Statements

"Safe Harbor" Statement under the Private Securities Litigation Reform Act of 1995

This presentation contains forward-looking statements, including, but not limited to, statements 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), including the timing and benefits 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 Luvox CR® products and its ability to increase sales of its Xyrem; 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; and Jazz Pharmaceuticals' ability to complete the transaction with Azur Pharma on the proposed terms and schedule and achieve the anticipated benefits of the transaction. These and those other applicable risks are described in more detail 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. Jazz Pharmaceuticals undertakes no duty or obligation to update any forward-looking statements contained in this presentation as a result of new information, future events or changes in its expectations.

Additional Information

Additional Information and Where to Find It

In connection with the proposed transaction between Jazz Pharmaceuticals and Azur Pharma, the companies have filed documents with the SEC, including the filing by Jazz Pharmaceuticals of a definitive proxy statement relating to the proposed transaction and related matters, and the filing by Azur Pharma of a registration statement on Form S-4 that includes the definitive proxy statement/prospectus relating to the proposed transaction and 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 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, or by directing a request to Jazz Pharmaceuticals' Investor Relations department at Jazz Pharmaceuticals, Inc., Attention: Investor Relations, 3180 Porter Drive, Palo Alto, California 94304, 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 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.

For full prescribing information refer to product websites.

Building Shareholder Value by Focusing on Patient Needs

Jazz Pharmaceuticals' mission is to improve patients' lives by identifying, developing and commercializing valuable pharmaceutical products in focused therapeutic areas

Strategy to Build Shareholder Value

4 **Maintain entrepreneurial, ownership culture at the company**

Make disciplined resource allocation decisions

Jazz Pharmaceuticals

Current Business Overview

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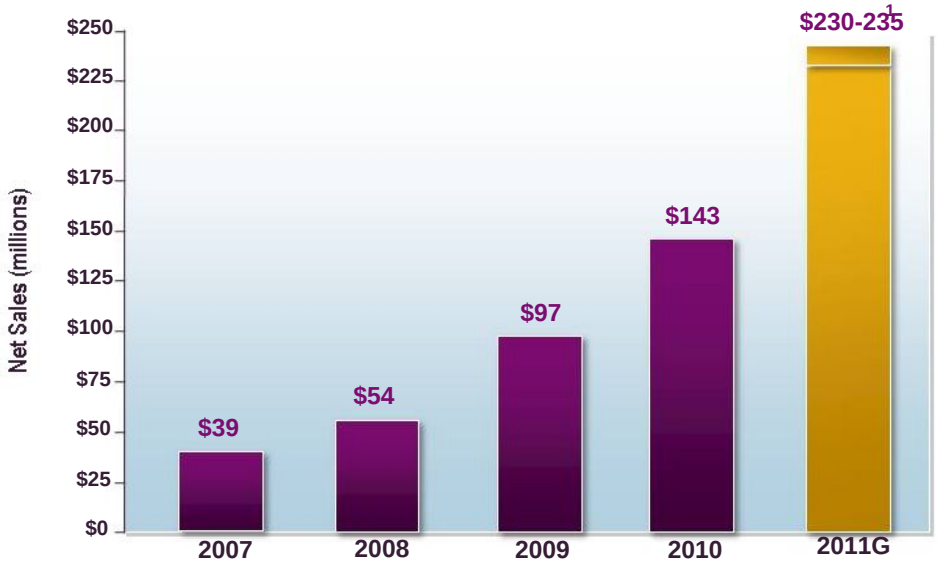
Xyrem - Strong Sales Growth



1. Based on guidance provided on November 1, 2011. The company is not updating the prior guidance and actual results may differ.

Xyrem is a Standard of Care in Narcolepsy

- Only FDA-approved product for both cataplexy and excessive daytime sleepiness in patients with narcolepsy
  - Marketed in U.S. since 2002
  - Marketed in major European countries by UCB and in Canada by Valeant

- Currently marketed in U.S. by 110-person specialty sales force
- Over 9,000 patients on therapy, usually in conjunction with stimulant therapy
- Distributed under proprietary Xyrem Success Program®

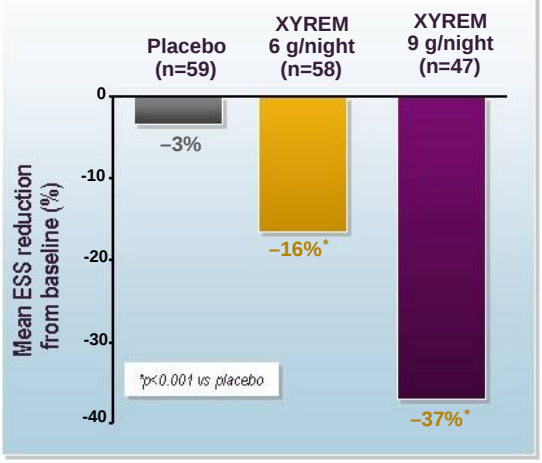
The Burden of Narcolepsy

- Affects 1 in 2000 in US[1]
  - ≈ multiple sclerosis and Parkinson's disease[2]
  - > cystic fibrosis[3]
- Although narcolepsy is thought to affect between 125,000 and 200,000 Americans, only about 50,000 are diagnosed[4]
- Key symptoms can be debilitating
  - Cataplexy occurs in 60%-100% of patients
  - 100% experience excessive daytime sleepiness

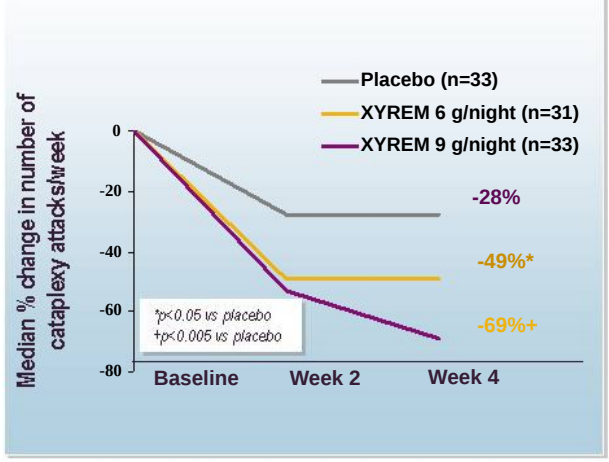
1. National Institute of Neurological Disorders and Stroke. http://www.ninds.nih.gov/disorders/narcolepsy/detail_narcolepsy.htm. Accessed March 17, 2011.
2. Narcolepsy Sleep Foundation. www.sleepfoundation.org/article/sleep-related-problems/narcolepsy-and-sleep. Accessed March 17, 2011.
3. Zemanick et al. J Cyst Fibros. 2010;9:1-16.
4. American Sleep Association. http;//www.sleepassociation.org/index.php?p=aboutnarcolepsy. Accessed March 17, 2011.

Xyrem has Demonstrated Effect on Two Key Symptoms of Narcolepsy

Improvement in Epworth Sleepiness Scale[1]



Reduction in Weekly Cataplexy Attacks[2]



1. Trial 3: From a 8-week, multicenter, randomized, double-blind, placebo-controlled, parallel-arm trial of narcolepsy patients (N=228) with moderate to severe EDS and cataplexy symptoms. Antidepressants were withdrawn prior to randomization and stimulants were continued throughout the study at stable doses. In XYREM clinical trials, ≈80% of patients maintained concomitant stimulant use. XYREM International Study Group. *J Clin Sleep Med* 2005;1:391.
2. Trial 1: From a 4-week, double-blind, placebo-controlled trial of narcolepsy patients (N=136) with moderate to severe cataplexy (median of 21 attacks per week) comparing the effects of three doses of orally administered sodium oxybate with placebo for the treatment of narcolepsy. Patients continued to receive stable stimulant therapy throughout the study. The US XYREM Multicenter Study Group. *Sleep* 2002;25(1):42-29.

Jazz Pharmaceuticals

Most Common Adverse Events in Controlled Studies of Xyrem

Adverse Event[1]	% of Patients (N=655)	
	Placebo[2]	Xyrem[3]
Nausea	4	19
Dizziness	4	18
Headache	15	18
Vomiting	1	8
Somnolence	4	6
Urinary incontinence[4]	<1	6
Nasopharyngitis	5	6

Label includes boxed warning that sodium oxybate is a central nervous system depressant with abuse potential and should not be used with alcohol or other CNS depressants. See complete boxed warning at end of presentation.

1. Occurring in ≥5% of XYREM patients and more frequently than with placebo. 2. Data on file, Jazz Pharmaceuticals, Inc. 3. XYREM (sodium oxybate) PI. 4. Generally nocturnal enuresis.

Update on FDA Form 483 and Related Warning Letter

- Fully committed to accurate and timely adverse event (AE) reporting
- After receipt of FDA Form 483 in May, immediate actions initiated to improve AE reporting procedures:
  - Implemented additional procedures at central pharmacy
  - Strengthened AE collection and reporting systems, including revised SOPs
  - Improved training and auditing programs
- Timely response to October FDA warning letter submitted
- Ongoing oversight strengthened to ensure robust safety reporting systems

Strong Sodium Oxybate Patent Coverage

	Number	Issue Date	Expiration Date
Distribution system patent*	7,765,106	7/27/2010	6/16/2024
Distribution system patent*	7,765,107	7/27/2010	6/16/2024
Distribution system patent	7,797,171	9/14/2010	6/16/2024
Distribution system patent*	7,668,730	2/23/2010	6/16/2024
Distribution system patent*	7,895,059	2/23/2011	12/17/2022
Formulation patent*	6,780,889	8/24/1999	7/4/2020
Formulation patent*	7,262,219	8/28/2007	7/4/2020
Process patent	6,472,431	10/29/1999	12/22/2019
Method of use patent*	7,851,506	12/14/2010	12/22/2019

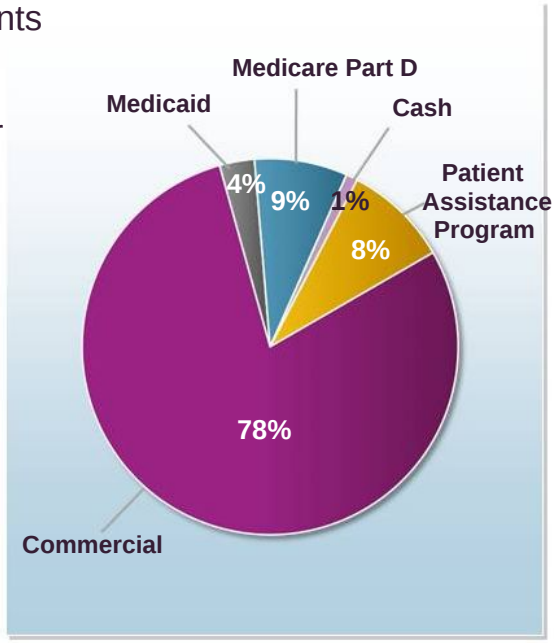
* Listed in FDA Orange Book

Overview of Manufacturing and Distribution

- DEA drug quota needed to manufacture controlled “Schedule I” API
- Exclusive relationships with API supplier and finished goods manufacturer:
  - Siegfried approved by FDA for API supply
- Unique proprietary distribution system uses exclusive single pharmacy
- Risk management program and unique product attributes require high touch capabilities

Current Xyrem Patient Coverage Distribution*

- Approximately 90% of insured patients have access
- Relatively low rates of required prior authorizations
- Low monthly out-of-pocket (OOP) expenses
  - Over 70% of patients have monthly OOP of ≤ $50



* Company data and MediMedia Formulary Compass: Sep/Oct 2011.

Xyrem Growth Initiatives

Increased Marketing Investment

- New narcolepsy physician targets
- Xyrem Success Program education
- Patient services
  - Nursing program
  - Xyrem Patient Connection
  - Patient assistance programs

Improve Market Penetration Over Time

Current Patients >9,000
Approximately 18% of 50K Diagnosed Narcolepsy Patients

Luvox CR® - Important Treatment Option for OCD

- Indicated for obsessive compulsive disorder (OCD)
- OCD affects ~ 2.2 million Americans[1,2]
  - Often underdiagnosed[3,4]
  - Difficult to differentiate from comorbidities[5]
- Only 43% of adults newly diagnosed with OCD received adequate treatment in the year after their first visit for OCD[6]

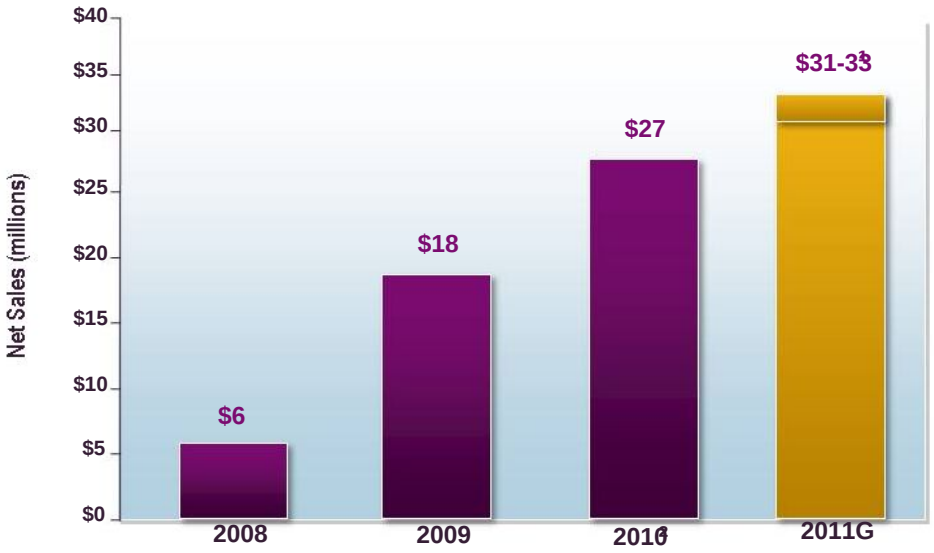
LUVOX CR®
fluvoxamine maleate extended-release capsules

Label includes boxed warning regarding suicidality and antidepressant drugs. See complete boxed warning at end of presentation.

1. National Institute of Mental Health. http://www.nimh.nih.gov/health/publications/the-numbers-count-mental-disorders-in-america.shtml. Accessed March 3, 2008. 2. Kessler RC, et al. Arch Gen Psychiatry. 2005;62:617-627. 3. Fireman B, et al. Am J Psychiatry. 2001;158:1904-1910. 4. Grabill K et al..Assessment of obsessive-compulsive disorder: a review.J Anxiety Disord. 2008;22(1):1-17. 5. Hales RE, et al (eds). Textbook of Psychiatry. 1999:600-610. 6. Koran LM, et al. Am J Health Syst Pharm. 2000;57:1972-1978.

Jazz Pharmaceuticals

Luvox CR – Continued Sales Growth



1. Based on guidance provided on November 1, 2011. The company is not updating the prior guidance and actual results may differ.
2. Includes $2 million of revenue recorded as a result of a change in the timing of when Luvox CR revenue is recognized. The company now records sales upon shipment to distributors net of estimated returns.

2011 Guidance Reflects High Operating Leverage

	2010A	2011G[1]
Total Product Sales	**$170M**	**$261 - 268M**
Xyrem	$143M	$230 - 235M
Luvox CR	$27M	$31 - 33M
SG&A and R&D Combined[2]	**$95M**	**$114 - 118M**
GAAP Net Income	**$33M**	**$128 - 131M**
Adjusted Net Income[3]	**$61M**	**$160 - 163M**
GAAP EPS	**$0.83**	**$2.76 - $2.81**
Adjusted EPS[3]	**$1.55**	**$3.45 - $3.50**

1. Based on guidance provided on November 1, 2011. The company is not updating the prior guidance and actual results may differ.
2. Includes Azur transaction related expenses of $10-11 million.
3. Adjusted net income and adjusted EPS are non-GAAP financial measures that exclude certain items from GAAP net income and GAAP EPS. A reconciliation of adjusted net income to GAAP net income and the related per share amounts is in a table included with this presentation.

Strategic Transaction with Azur Pharma

AZUR PHARMA

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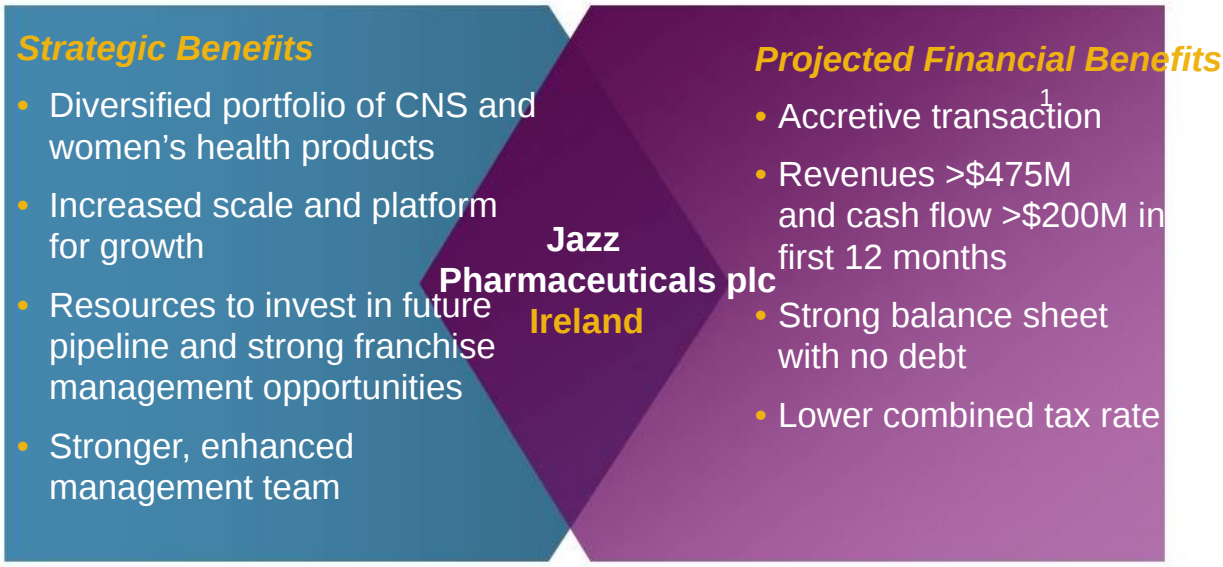
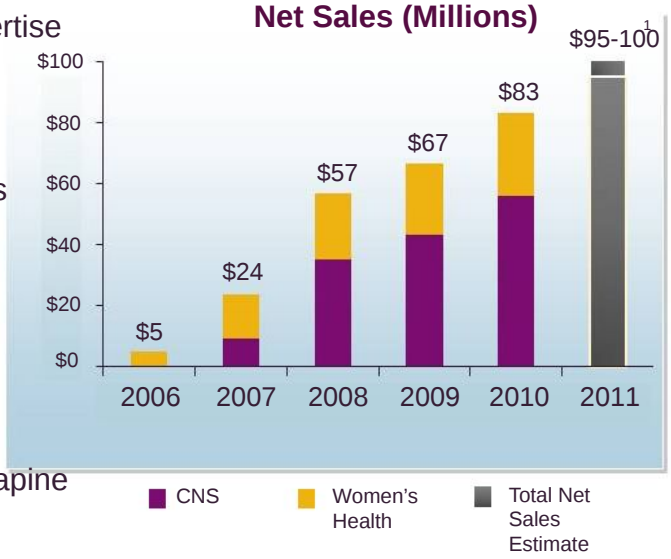
Compelling Strategic and Financial Benefits



[1] Accretion for Jazz Pharmaceuticals shareholders is on a fully-taxed adjusted EPS basis. Adjusted EPS is a non-GAAP financial measure that excludes certain items from GAAP EPS.

Azur Pharma – Compelling Fit with Jazz Pharmaceuticals

- Strong commercial focus and expertise in CNS and women's health
- Approximately 170 employees:
  - 105 people in 3 US sales forces across pain, psychiatry and women's health
  - 16 person medical affairs team
  - 50 people in home office (18 Dublin; 32 Philadelphia)
- Pipeline of line extensions for clozapine franchise



1. Based on estimate provided on September 19, 2011. The estimate is not being updated.

Prialt - for Chronic Pain

- 2010 net sales of $20M (marketed by Azur since May 2010)
- Only non-opioid intrathecal (IT) analgesic for severe chronic pain[1]
- Compelling growth opportunity with similar characteristics to Xyrem:
  - Requires high touch sales capability with heavy clinical emphasis
  - Currently used in less than 3% of available pain market pumps (approximately 1500)
  - Limited competitive threats and multiple years of patent and other protection
- European rights licensed to Eisai; Azur retains ROW rights

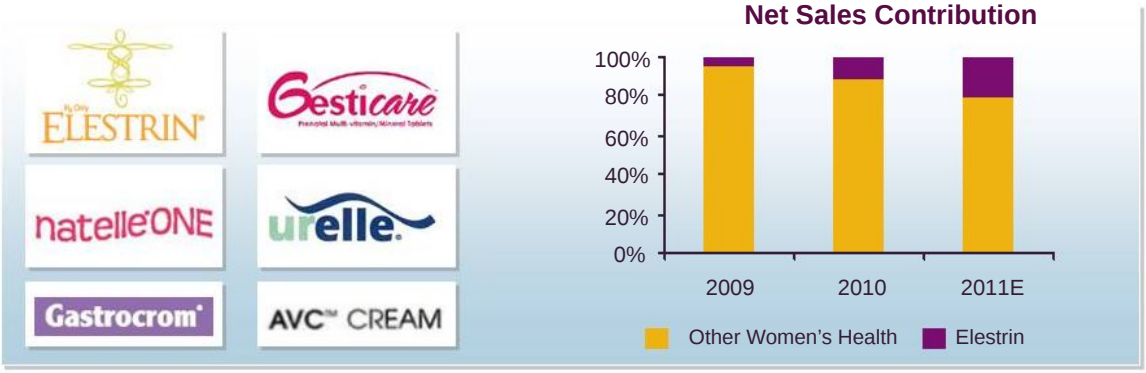
1. See full prescribing information on website

FazaClo – for Treatment Resistant Schizophrenia

- 2010 net sales of $37M
- Orally disintegrating clozapine tablets approved for management of treatment resistant schizophrenia[1]
- Approximately 10% prescription share despite largely generic clozapine market
- FazaClo High Dose (HD) launched September 2010
  - More than 27% switched from Low Dose (LD) as of 3Q11
  - Dosing flexibility and lower pill burden
- Generics filed to FazaClo – settlement with Teva with potential launch of lower dosage product in July 2012 and HD in 2015
- Additional clozapine line extensions in development

1. See full prescribing information on website

Women's Health Products - Targeting a Growing Market



- Diversified and balanced set of six products with 2010 net sales of $27M
- Significant growth opportunity driven by Elestrin[1], a topical gel ERT therapy
  - Patents through 2022
- Revamped Elestrin promotion model in 2010 leveraging ~ 50 sales representatives

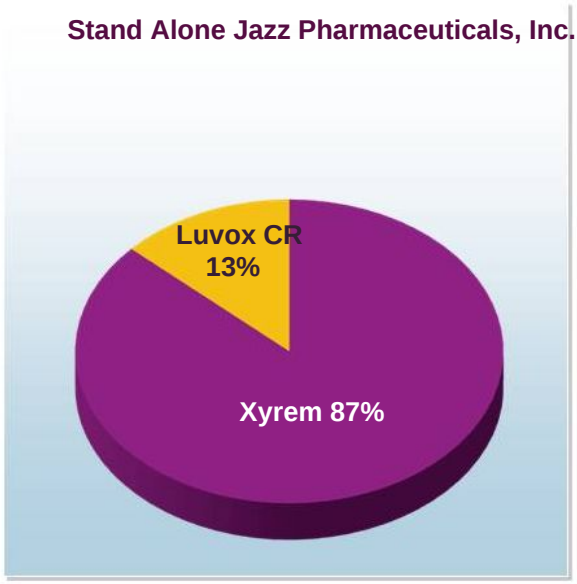
1. See full prescribing information on website

Jazz Pharmaceuticals

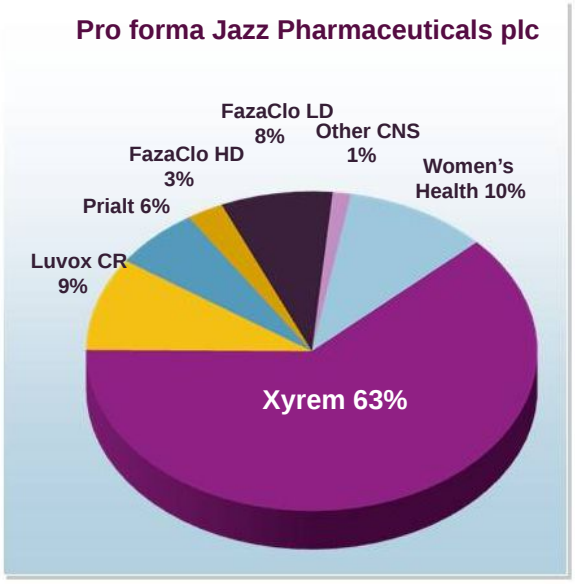
A Growing, Diversified Product Portfolio

2011 Estimated Net Sales

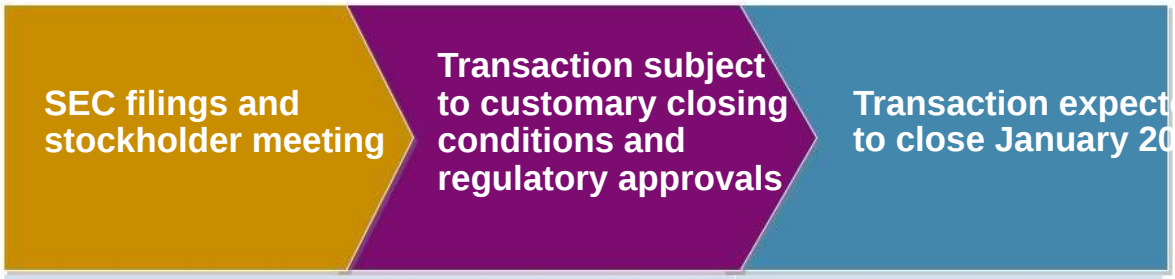
Stand Alone Jazz Pharmaceuticals, Inc.



Pro forma Jazz Pharmaceuticals plc



Transaction Closing on Track

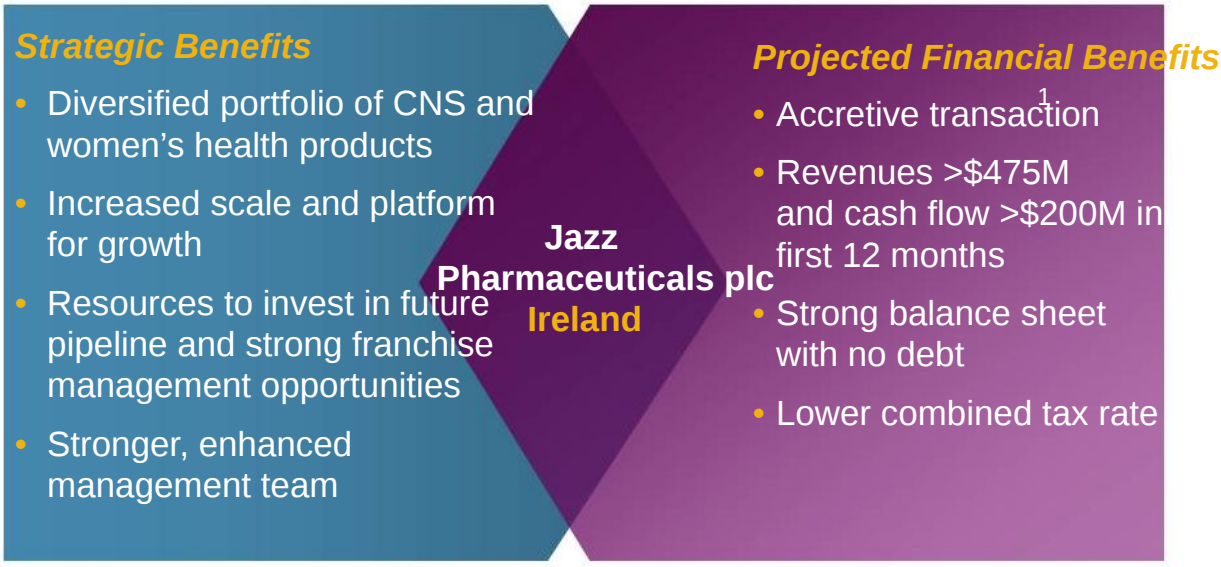


- Azur Pharma S-4 declared effective
- Proxy statement/prospectus mailed to Jazz Pharmaceuticals, Inc. stockholders in November
- Jazz Pharmaceuticals, Inc. stockholder meeting on December 12, 2011

- Azur approval of other necessary actions required
- US antitrust clearance pending

- Transaction taxable to Jazz Pharmaceuticals, Inc. stockholders
- Jazz Pharmaceuticals plc shares to be traded on Nasdaq under "JAZZ"

Compelling Strategic and Financial Benefits



[1] Accretion for Jazz Pharmaceuticals shareholders is on a fully-taxed adjusted EPS basis. Adjusted EPS is a non-GAAP financial measure that excludes certain items from GAAP EPS.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Reconciliation of GAAP Net Income and EPS to Adjusted Net Income and EPS in Financial Results and Guidance

	2010	2011G[1]
GAAP net income	$33	$128-131M
Add:		
Intangible asset amortization	8	7
Stock-based compensation expense	8	13
Non-cash interest expense and extinguishment of debt	14	2
Azur Pharma transaction related costs	-	10-11
Deduct:		
Contract revenues	(1)	(1)
Luvox CR revenue recognition timing change	(1)	-
Adjusted net income	$61	$160-163
GAAP net income per diluted share (EPS)	$0.83	$2.76-2.81
Adjusted net income per diluted share (EPS)	$1.55	$3.45-3.50
Shares used in computing GAAP and adjusted net income per diluted share amounts	39	46-47

(In millions, except per share amounts)

1. Based on guidance provided on November 1, 2011. The company is not updating the prior guidance and actual results may differ.

Xyrem (sodium oxybate) Boxed Warning

!WARNING: Central nervous system depressant with abuse potential.
Should not be used with alcohol or other CNS depressants.

Sodium oxybate is GHB, a known drug of abuse. Abuse has been associated with some important central nervous system (CNS) adverse events (including death). Even at recommended doses, use has been associated with confusion, depression and other neuropsychiatric events. Reports of respiratory depression occurred in clinical trials. Almost all of the patients who received sodium oxybate during clinical trials were receiving CNS stimulants.

Important CNS adverse events associated with abuse of GHB include seizure, respiratory depression and profound decreases in level of consciousness, with instances of coma and death. For events that occurred outside of clinical trials, in people taking GHB for recreational purposes, the circumstances surrounding the events are often unclear (e.g., dose of GHB taken, the nature and amount of alcohol or any concomitant drugs).

Xyrem is available through the Xyrem Success Program, using a centralized pharmacy (1-866-XYREM-88 (1-866-997-3688)). The Success Program provides educational materials to the prescriber and the patient explaining the risks and proper use of sodium oxybate, and the required prescription form. Once it is documented that the patient has read and/or understood the materials, the drug will be shipped to the patient. The Xyrem Success Program also recommends patient follow-up every 3 months. Physicians are expected to report all serious adverse events to the manufacturer. (See WARNINGS).

XYREM (sodium oxybate) PI

Luvox CR (fluvoxamine maleate) Boxed Warning

Suicidality and Antidepressant Drugs

Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents, and young adults in short-term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of LUVOX CR® (fluvoxamine maleate) Extended-Release Capsules or any other antidepressant in a child, adolescent, or young adult must balance this risk with the clinical need. Short-term studies did not show an increase in the risk of suicidality with antidepressants compared to placebo in adults beyond age 24; there was a reduction in risk with antidepressants compared to placebo in adults aged 65 and older. Depression and certain other psychiatric disorders are themselves associated with increases in the risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber. LUVOX CR Capsules are not approved for use in pediatric patients. (See WARNINGS: Clinical Worsening and Suicide Risk, PRECAUTIONS: Information for Patients, and PRECAUTIONS: Pediatric Use.)

LUVOX CR (fluvoxamine maleate) PI

Prialt (ziconotide intrathecal infusion) Boxed Warning

WARNING:

Severe psychiatric symptoms and neurological impairment may occur during treatment with PRIALT. Patients with a pre-existing history of psychosis should not be treated with PRIALT. All patients should be monitored frequently for evidence of cognitive impairment, hallucinations, or changes in mood or consciousness. PRIALT therapy can be interrupted or discontinued abruptly without evidence of withdrawal effects in the event of serious neurological or psychiatric signs or symptoms

FazaClo (clozapine) Boxed Warning

WARNING:

1. AGRANULOCYTOSIS

BECAUSE OF A SIGNIFICANT RISK OF AGRANULOCYTOSIS, A POTENTIALLY LIFE-THREATENING ADVERSE EVENT, CLOZAPINE SHOULD BE RESERVED FOR USE IN (1) THE TREATMENT OF SEVERELY ILL PATIENTS WITH SCHIZOPHRENIA WHO FAIL TO SHOW AN ACCEPTABLE RESPONSE TO ADEQUATE COURSES OF STANDARD ANTIPSYCHOTIC DRUG TREATMENT, OR (2) FOR REDUCING THE RISK OF RECURRENT SUICIDAL BEHAVIOR IN PATIENTS WITH SCHIZOPHRENIA OR SCHIZOAFFECTIVE DISORDER WHO ARE JUDGED TO BE AT RISK OF REEXPERIENCING SUICIDAL BEHAVIOR. PATIENTS BEING TREATED WITH CLOZAPINE MUST HAVE A BASELINE WHITE BLOOD CELL (WBC) COUNT AND ABSOLUTE NEUTROPHIL COUNT (ANC) BEFORE INITIATION OF TREATMENT AS WELL AS REGULAR WBC COUNTS AND ANCs DURING TREATMENT AND FOR AT LEAST 4 WEEKS AFTER DISCONTINUATION OF TREATMENT. (SEE WARNINGS.) CLOZAPINE IS AVAILABLE ONLY THROUGH A DISTRIBUTION SYSTEM THAT ENSURES MONITORING OF WBC COUNTS AND ANCs ACCORDING TO THE SCHEDULE DESCRIBED BELOW PRIOR TO DELIVERY OF THE NEXT SUPPLY OF MEDICATION. (SEE WARNINGS.)

2. SEIZURES

SEIZURES HAVE BEEN ASSOCIATED WITH THE USE OF CLOZAPINE. DOSE APPEARS TO BE AN IMPORTANT PREDICTOR OF SEIZURE, WITH A GREATER LIKELIHOOD AT HIGHER CLOZAPINE DOSES. CAUTION SHOULD BE USED WHEN ADMINISTERING CLOZAPINE TO PATIENTS HAVING A HISTORY OF SEIZURES OR OTHER PREDISPOSING FACTORS. PATIENTS SHOULD BE ADVISED NOT TO ENGAGE IN ANY ACTIVITY WHERE SUDDEN LOSS OF CONSCIOUSNESS COULD CAUSE SERIOUS RISK TO THEMSELVES OR OTHERS. (SEE WARNINGS.)

3. MYOCARDITIS

ANALYSES OF POSTMARKETING SAFETY DATABASES SUGGEST THAT THAT CLOZAPINE IS ASSOCIATED WITH AN INCREASED RISK OF FATAL MYOCARDITIS, ESPECIALLY DURING, BUT NOT LIMITED TO, THE FIRST MONTH OF THERAPY. IN PATIENTS IN WHOM MYOCARDITIS IS SUSPECTED, CLOZAPINE TREATMENT SHOULD BE PROMPTLY DISCONTINUED. (SEE WARNINGS.)

FazaClo (clozapine) Boxed Warning - continued

4. OTHER ADVERSE CARDIOVASCULAR AND RESPIRATORY EFFECTS

ORTHOSTATIC HYPOTENSION, WITH OR WITHOUT SYNCOPE, CAN OCCUR WITH CLOZAPINE TREATMENT. RARELY, COLLAPSE CAN BE PROFOUND AND BE ACCOMPANIED BY RESPIRATORY AND/OR CARDIAC ARREST. ORTHOSTATIC HYPOTENSION IS MORE LIKELY TO OCCUR DURING INITIAL TITRATION IN ASSOCIATION WITH RAPID DOSE ESCALATION. IN PATIENTS WHO HAVE HAD EVEN A BRIEF INTERVAL OFF CLOZAPINE (ie, 2 OR MORE DAYS SINCE THE LAST DOSE) TREATMENT SHOULD BE STARTED WITH 12.5 MG ONCE OR TWICE DAILY. (SEE WARNINGS AND DOSAGE AND ADMINISTRATION.) SINCE COLLAPSE, RESPIRATORY ARREST, AND CARDIAC ARREST DURING INITIAL TREATMENT HAS OCCURRED IN PATIENTS WHO WERE BEING ADMINISTERED BENZODIAZEPINES OR OTHER PSYCHOTROPIC DRUGS, CAUTION IS ADVISED WHEN CLOZAPINE IS INITIATED IN PATIENTS TAKING A BENZODIAZEPINE OR ANY OTHER PSYCHOTROPIC DRUG. (SEE WARNINGS.)

5. INCREASED MORTALITY IN ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS

ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS TREATED WITH ANTIPSYCHOTIC DRUGS ARE AT AN INCREASED RISK OF DEATH. ANALYSES OF SEVENTEEN PLACEBO-CONTROLLED TRIALS (MODAL DURATION OF 10 WEEKS), LARGELY IN PATIENTS TAKING ATYPICAL ANTIPSYCHOTIC DRUGS, REVEALED A RISK OF DEATH IN DRUG-TREATED PATIENTS OF BETWEEN 1.6 TO 1.7 TIMES THE RISK OF DEATH IN PLACEBO-TREATED PATIENTS. OVER THE COURSE OF A TYPICAL 10-WEEK CONTROLLED TRIAL, THE RATE OF DEATH IN DRUG-TREATED PATIENTS WAS ABOUT 4.5%, COMPARED TO A RATE OF ABOUT 2.6% IN THE PLACEBO GROUP. ALTHOUGH THE CAUSES OF DEATH WERE VARIED, MOST OF THE DEATHS APPEARED TO BE EITHER CARDIOVASCULAR (eg, HEART FAILURE, SUDDEN DEATH) OR INFECTIOUS (eg, PNEUMONIA) IN NATURE. OBSERVATIONAL STUDIES SUGGEST THAT, SIMILAR TO ATYPICAL ANTIPSYCHOTIC DRUGS, TREATMENT WITH CONVENTIONAL ANTIPSYCHOTIC DRUGS MAY INCREASE MORTALITY. THE EXTENT TO WHICH THE FINDINGS OF INCREASED MORTALITY IN OBSERVATIONAL STUDIES MAY BE ATTRIBUTED TO THE ANTIPSYCHOTIC DRUG AS OPPOSED TO SOME CHARACTERISTICS OF THE PATIENTS IS NOT CLEAR. FAZACLO® (clozapine, USP) IS NOT APPROVED FOR THE TREATMENT OF PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS. (SEE WARNINGS.)


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