JAZZ PHARMACEUTICALS INC
Form 425
December 08, 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 is a slide presentation relating to the proposed transactions described therein that was made available beginning on December 7, 2011.

December 7, 2011
Investor Relations

Forward-Looking Statements
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.

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

3

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 t 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 be

mailed to Jazz Pharmaceuticals stockholders in connection with the proposed transaction. INVESTORS AND SECURITY H
ARE URGED TO READ THE REGISTRATION STATEMENT ON FORM S-4 AND THE RELATED DEFINITIVE PROX
STATEMENT/PROSPECTUS BECAUSE THEY CONTAIN IMPORTANT INFORMATION ABOUT JAZZ PHARMACEU
PHARMA, THE PROPOSED TRANSACTION AND RELATED MATTERS. Investors and security holders may obtain free
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
Pharmaceuticals Investor Relations department at Jazz Pharmaceuticals, Inc., Attention: Investor Relations, 3180 Porter Driv
California 94304, to Jazz Pharmaceuticals Investor Relations department at 650-496-2800 or by email to investorinfo@jazzp
Investors and security holders may obtain free copies of the documents filed with the SEC on Jazz Pharmaceuticals website a
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 m
deemed participants in the solicitation of proxies from the stockholders of Jazz Pharmaceuticals in connection with the propose
transaction. Information regarding the special interests of these directors and executive officers in the proposed transaction is i
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, whic
with the SEC on April 12, 2011. These documents are available free of charge at the SEC s web site and from Investor Relatio
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 off
subscribe for or buy, any securities nor shall there be any sale, issuance or transfer of securities in any jurisdiction in which suc
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

4

5
Pursue lower risk development of specialty products
Invest percentage of sales longer-term
3

Strategy to Build Shareholder Value
Grow Xyrem sales in
current indications
Increased focus on
achieving full potential
Acquire additional
marketed or close to
approval products
Leverage our expertise
and infrastructure
2
1
Maintain entrepreneurial, ownership culture at the company
4
Make disciplined resource allocation decisions

Current Business Overview

$39
$54
$97
$230-235
1
2010
2009

2008
2007
2011G
$143
$0
$25
$50
$75
$100
$175
$200
$125
$150
$225
$250
Xyrem -
Strong Sales Growth
7
1.
Based on guidance provided on November 1, 2011. The company is not updating the prior guidance and actual results may dif

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
®
8

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

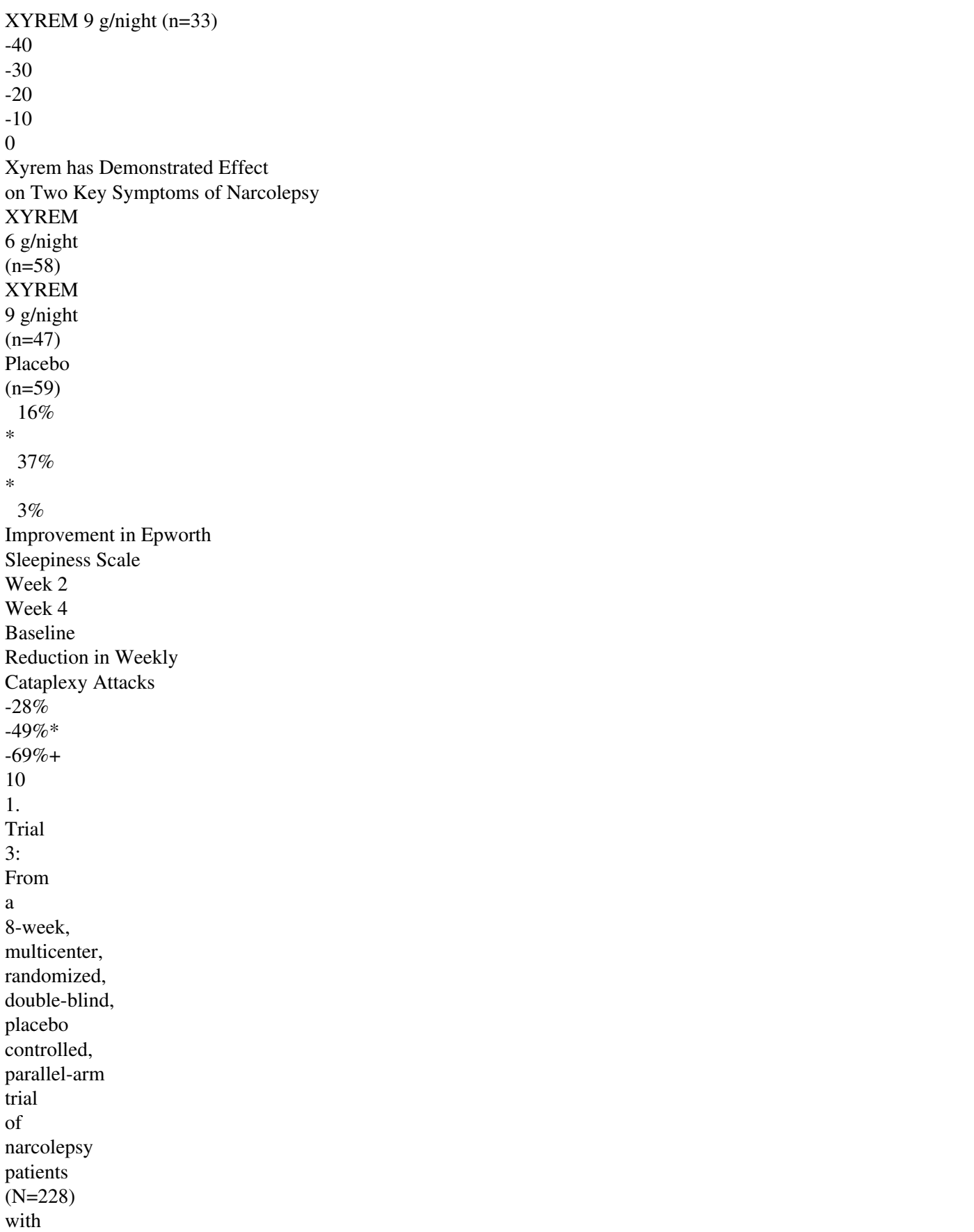
Key symptoms can be debilitating

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
2.
Narcolepsy Sleep Foundation. www.sleepfoundation.org/article/sleep-related-problems/narcolepsy-and-sleep. Accessed March
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.
9

-80
-60
-40
-20
0
Placebo (n=33)
XYREM 6 g/night (n=31)


XYREM 9 g/night (n=33)
-40
-30
-20
-10
0
Xyrem has Demonstrated Effect
on Two Key Symptoms of Narcolepsy
XYREM
6 g/night
(n=58)
XYREM
9 g/night
(n=47)
Placebo
(n=59)
16%
*
37%
*
3%
Improvement in Epworth
Sleepiness Scale
Week 2
Week 4
Baseline
Reduction in Weekly
Cataplexy Attacks
-28%
-49%*
-69%+
10
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 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.
1
2
Sleep Med.

Most Common Adverse Events in
Controlled Studies of Xyrem
Adverse Event
% 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.
11
1. Occurring in
5% of XYREM patients and more frequently than with placebo. 2. Data on file, Jazz Pharmaceuticals, Inc. 3. XYREM (sodiu
1

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

12

Strong Sodium Oxybate Patent Coverage
* Listed in FDA Orange Book
13
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

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

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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.
Medicare Part D
15
Commercial
8%
4%
1%
9%
Patient
Assistance
Program
Cash
Medicaid
78%

Xyrem Growth Initiatives
16

New narcolepsy physician targets

Xyrem Success Program education

Patient services
-
Nursing program
-
Xyrem Patient Connection
-
Patient assistance programs
Increased Marketing Investment
Improve Market Penetration Over Time
Current Patients >9,000
Approximately 18% of 50K Diagnosed Narcolepsy Patients

17

1. National Institute of Mental Health. http://www.nimh.nih.gov/health/publications/the-numbers-count-mental-disorders-in-ar
B, et al. Am J Psychiatry. 2001;158:1904-1910. 4. Grabill K et al..Assessment of obsessive-compulsive disorder: a review.J A

et al. Am J Health Syst Pharm. 2000;57:1972-1978.
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
Label includes boxed warning regarding suicidality and antidepressant drugs.
See complete boxed warning at end of presentation.

Luvox CR
Continued Sales Growth
$30
$6
$31-33
1
2009

2008
2011G
18
$0
$5
$10
$15
$20
$25
2010
2
$18
$35
$40
$27
1.
Based on guidance provided on November 1, 2011. The company is not updating the prior guidance and actual results may dif
2.
Includes $2 million of revenue recorded as a result of a change in the timing of when Luvox CR revenue is recognized. The co

19
2011 Guidance Reflects High Operating Leverage
1.
Based on guidance provided on November 1, 2011. The company is not updating the prior guidance and actual results may dif
2.
Includes Azur transaction related expenses of $10-11 million.
2010-

A
2011-
G
[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
Adjusted net income and adjusted EPS are non-GAAP financial measures that exclude certain items from GAAP net income ar
net income to GAAP net income and the related per share amounts is in a table included with this presentation.
3.

Strategic Transaction with
Azur Pharma

21
Strategic Benefits

Diversified portfolio of CNS and
women s health products

Increased scale and platform

for growth

Resources to invest in future
pipeline and strong franchise
management opportunities

Stronger, enhanced
management team
Projected Financial Benefits

Accretive transaction
1

Revenues >$475M
and cash flow >$200M in
first 12 months

Strong balance sheet
with no debt

Lower combined tax rate
1
Accretion for Jazz Pharmaceuticals shareholders is on a fully-taxed adjusted EPS basis. Adjusted EPS is a non-GAAP financia
Compelling Strategic and Financial Benefits
Jazz
Pharmaceuticals plc
Ireland

Azur Pharma
Compelling Fit with Jazz Pharmaceuticals
22
CNS
Women s
Health
Net Sales (Millions)

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.
$5
$24
$57
$67
$83
$95-100
Total Net
Sales
Estimate
$100
$80
$60
$40
$20
$0
2006
2007
2008
2009
2010
2011
1

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
23
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

24

1. See full prescribing information on website

25

Diversified and balanced set of six products
[1]
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
0%
20%
40%
60%
80%
100%
2009
2010
2011E
Women s Health Products -
Targeting a Growing Market
Elestrin
Other Women s Health
Net Sales Contribution
1. See full prescribing information on website

26
2011 Estimated Net Sales
Stand Alone Jazz Pharmaceuticals, Inc.
Pro forma Jazz Pharmaceuticals plc
A Growing, Diversified Product Portfolio
Luvox CR
13%

Xyrem 87%
Xyrem 63%
Luvox CR
9%
Prialt 6%
Women s
Health 10%
Other CNS
1%
FazaClo LD
8%
FazaClo HD
3%

27
Transaction Closing on Track
SEC filings and
stockholder meeting
Transaction expected
to close January 2012
Transaction subject

to customary closing conditions and regulatory approvals

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

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

28
Strategic Benefits

Diversified portfolio of CNS and
women s health products

Increased scale and platform

for growth

Resources to invest in future
pipeline and strong franchise
management opportunities

Stronger, enhanced
management team
Projected Financial Benefits

Accretive transaction
1

Revenues >$475M
and cash flow >$200M in
first 12 months

Strong balance sheet
with no debt

Lower combined tax rate
1
Accretion for Jazz Pharmaceuticals shareholders is on a fully-taxed adjusted EPS basis. Adjusted EPS is a non-GAAP financia
Compelling Strategic and Financial Benefits
Jazz
Pharmaceuticals plc
Ireland

30
2011G
1
2010
Reconciliation of GAAP Net Income and EPS to Adjusted
Net Income and EPS in Financial Results and Guidance
(In millions, except per share amounts)
GAAP net income

Add:
Intangible asset amortization
Stock-based compensation expense
Non-cash interest expense and extinguishment of debt
Azur Pharma transaction related costs
Deduct:
Contract revenues
GAAP net income per diluted share (EPS)
Adjusted net income per diluted share (EPS)
Shares used in computing GAAP and adjusted net
income per diluted share amounts
Adjusted net income
Luvox CR revenue recognition timing change
(1)
$128-131M
7
13
2
$160-163
$2.76-2.81
$3.45-3.50
46-47
10-11
(1)
$33
8
8
14
$61
$0.83
$1.55
39
(1)
1.
Based on guidance provided on November 1, 2011. The company is not updating the prior guidance and actual results may dif
-
-

31
Xyrem
(sodium oxybate)
Boxed Warning
XYREM (sodium oxybate) PI
!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-XYREM88 ® (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).

Luvox CR
(fluvoxamine maleate)
Boxed Warning
LUVOX CR (fluvoxamine maleate) PI
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 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.)
disorders.
Anyone
considering
the
use
of
LUVOX
CR
®
(fluvoxamine
maleate)

Prialt
(ziconotide intrathecal infusion)
Boxed 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
Prialt (ziconotide intrathecal infusion) PI
WARNING:

FazaClo
(clozapine)
Boxed Warning
1. AGRANULOCYTOSIS
BECAUSE OF A SIGNIFICANT RISK OF AGRANULOCYTOSIS, A POTENTIALLY LIFE-THREATENING ADVERSE
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
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 BASE
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
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 SHOULI
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 SUD
LOSS OF CONSCIOUSNESS COULD CAUSE SERIOUS RISK TO THEMSELVES OR OTHERS. (SEE WARNINGS.)
3. MYOCARDITIS
ANALYSES OF POSTMARKETING SAFETY DATABASES SUGGEST THAT THATCLOZAPINE IS ASSOCIATED WI
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) PI
WARNING:

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 W
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 WA
AND DOSAGE AND ADMINISTRATION.) SINCE COLLAPSE, RESPIRATORY ARREST, AND CARDIAC ARREST D
INITIAL TREATMENT HAS OCCURRED IN PATIENTS WHO WERE BEING ADMINISTERED BENZODIAZEPINES
OTHER PSYCHOTROPIC DRUGS, CAUTION IS ADVISED WHEN CLOZAPINE IS INITIATED IN PATIENTS TAKIN
BENZODIAZEPINE OR ANY OTHER PSYCHOTROPIC DRUG. (SEE WARNINGS.)
5.
INCREASED
MORTALITY
IN
ELDERLY
PATIENTS
WITH
DEMENTIARELATED
PSYCHOSIS
ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS TREATED WITH ANTIPSYCHOTIC DRUGS ARE A
INCREASED RISK OF DEATH. ANALYSES OF SEVENTEEN PLACEBO-CONTROLLED TRIALS (MODAL DURATI
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 PATIE
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
FAILURE,
SUDDEN
DEATH)
OR
INFECTIOUS
(eg,
PNEUMONIA)
IN
NATURE.
OBSERVATIONAL STUDIES SUGGEST
THAT, SIMILAR TO ATYPICAL ANTIPSYCHOTIC DRUGS, TREATMENT WITH CONVENTIONAL ANTIPSYCHOT
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
CHARACTERISTIC(S)
OF
THE
PATIENTS
IS
NOT
CLEAR.
FAZACLO®
(clozapine, USP) IS NOT APPROVED FOR THE
TREATMENT OF PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS. (SEE WARNINGS.)
FazaClo (clozapine) PI