

Edgar Filing: JAZZ PHARMACEUTICALS INC - Form 425

JAZZ PHARMACEUTICALS INC

Form 425

October 18, 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

The following is a slide presentation relating to the proposed transactions described therein that was made available beginning on October 18, 2011.

Bruce Cozadd  
Chairman and CEO  
October 18, 2011  
Introduction to Jazz Pharmaceuticals

2

Forward-Looking Statements

This presentation contains forward-looking statements, including, but not limited to, statements related to the anticipated consummation of the business combination transaction between Jazz Pharmaceuticals and Azur Pharma and the timing and benefits thereof, the combined company's, and each respective company's, strategy, plans, objectives, expectations (financial

or

otherwise)  
and  
intentions,  
future  
financial  
results  
and  
growth  
potential  
(including  
Jazz  
Pharmaceuticals  
2011

Financial Guidance), anticipated product portfolio, development programs, intellectual property and tax position, management structure, and other statements that are not historical facts. These forward-looking statements are based on Jazz Pharmaceuticals' current expectations and inherently involve significant risks and uncertainties. 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  
ability  
to  
complete  
the  
transaction

on the proposed terms and schedule; risks associated with business combination transactions, such as the risk that the businesses will not be integrated successfully or that such integration may be more difficult, time-consuming or costly than expected; risks related to future opportunities and plans for the combined company, including uncertainty of the expected financial performance and results of the combined company following completion of the proposed transaction; disruption from the proposed transaction, making it more difficult to conduct business as usual or maintain relationships with customers, employees or suppliers; the calculations of, and factors that may impact the calculations of, the acquisition price in connection with the proposed merger and the allocation of such acquisition price to the net assets acquired in accordance with applicable accounting rules and methodologies; and the possibility that if the combined company does not achieve the perceived benefits of the proposed transaction as rapidly or to the extent anticipated by financial analysts or investors, the market price of the combined company's shares could decline, as well as other risks related to Jazz Pharmaceuticals business,

including  
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; and those risks detailed from time-to-time  
under  
the  
caption  
Risk  
Factors  
and  
elsewhere  
in  
Jazz  
Pharmaceuticals  
SEC filings and reports, including in its Quarterly  
Report on Form 10-Q for the quarter ended June 30, 2011. 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.

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

3  
Additional Information  
In  
connection  
with  
the  
proposed

business  
combination  
transaction  
described  
in  
this  
presentation,  
Jazz  
Pharmaceuticals  
and  
Azur  
Pharma  
will  
be  
filing  
documents  
with  
the  
SEC,  
including  
the  
filing  
by  
Jazz  
Pharmaceuticals  
of  
a  
preliminary  
and  
definitive proxy statement/prospectus relating to the proposed transaction and the filing by Azur Pharma of a registration  
statement on Form S-4 that will include the proxy statement/prospectus relating to the proposed transaction. After the  
registration  
statement  
has  
been  
declared  
effective  
by  
the  
SEC,  
a  
definitive  
proxy  
statement/prospectus  
will  
be  
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  
DEFINITIVE PROXY/PROSPECTUS WHEN THEY BECOME AVAILABLE BECAUSE THEY WILL CONTAIN IMPOR

INFORMATION ABOUT JAZZ PHARMACEUTICALS, AZUR PHARMA AND THE PROPOSED TRANSACTION. Inve

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](http://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](mailto: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](http://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 will be 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.

For full prescribing information refer to product websites.

Additional Information and Where to Find It

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



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

Maintain entrepreneurial, ownership culture at the company

Make disciplined resource allocation decisions

1

3

4

Current Business and Financial  
Overview



\$39  
\$54  
\$97  
\$215-225  
2010  
2009  
2008

2007

2011G

\$143

Xyrem -

Strong Sales Growth

2011 Guidance \$215M-\$225M

8%

7

\$0

\$25

\$50

\$75

\$100

\$175

\$200

\$125

\$150

\$225

\$250

1.

Based on guidance provided on July 28, 2011. The company is not updating the prior guidance and actual results may differ.

1

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

Approximately 8,700 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

9

1.

National Institute of Neurological Disorders and Stroke. [http://www.ninds.nih.gov/disorders/narcolepsy/detail\\_narcolepsy.htm](http://www.ninds.nih.gov/disorders/narcolepsy/detail_narcolepsy.htm)

2.

Narcolepsy Sleep Foundation. [www.sleepfoundation.org/article/sleep-related-problems/narcolepsy-and-sleep](http://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.

-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

1

Week 2

Week 4

Baseline

Reduction in Weekly  
Cataplexy Attacks

2

\*p<0.001 vs placebo

\*p<0.05 vs placebo

+p<0.005 vs placebo

-28%

-49%\*

-69%+

10

-80

-60

-40

-20

0

Placebo (n=33)

XYREM 6 g/night (n=31)

XYREM 9 g/night (n=33)

Trial 3: From a 8-week, multicenter, randomized, double-blind, placebo controlled, parallel-arm trial of narcolepsy patients (N=136) with moderate to severe cataplexy.

Trial 1: From a 4-week, double-blind, placebo-controlled trial of narcolepsy patients (N=136) with moderate to severe cataplexy. Patients continued to receive stable stimulant therapy throughout the study.

1.

2.

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.



Most Common Adverse Events in  
Controlled Studies of Xyrem

Adverse Event

% of Patients (N=655)

Placebo

Xyrem

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  
2  
3

1. Occurring in 5% of XYREM patients and more frequently than with placebo. 2. Data on file, Jazz Pharmaceuticals, Inc.

Strong Sodium Oxybate Patent Coverage

\* Listed in FDA Orange Book

12

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



Unique proprietary distribution system uses exclusive single pharmacy

Risk management program and unique product attributes require high touch commercial capabilities

13

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  
79%  
8%  
3%  
1%  
9%

\* Company

data  
and  
MediMedia  
Formulary  
Compass  
July  
2011.  
Commercial  
Medicaid  
Medicare Part D  
Patient Asst  
Program  
Cash  
14

15

New narcolepsy physician targets

Xyrem Success Program education

Patient services

-

Nursing program

-

Xyrem Patient Connection

-

Patient assistance programs

Increased Marketing Investment

Xyrem Growth Initiatives

Improve Market Penetration Over Time

Current Patients = ~ 8,700

Approximately 17% of 50K Diagnosed Narcolepsy Patients



-  
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.

1. National Institute of Mental Health. <http://www.nimh.nih.gov/health/publications/the-numbers-count-mental-disorders-in-americans>  
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 Clin Psychiatry. 1999;60:600-610. 6. Koran LM, et al. Am J Health Syst Pharm. 2000;57:1972-1978.

Luvox CR  
Continued Sales Growth  
2011 Guidance \$32M-\$35M  
1  
\$30  
\$6  
\$32-35



2009  
2008  
2011G  
17  
\$0  
\$5  
\$10  
\$15  
\$20  
\$25  
2010  
\$18  
\$35  
\$40  
\$27

1.  
Based on guidance provided on July 28, 2011. The company is not updating the prior guidance and actual results may differ.
  2.  
Includes \$2.0 million of revenue recorded as a result of a change in the timing of when Luvox CR revenue is recognized. The c  
returns.
- 2

18

2011 Guidance Reflects High Operating Leverage

1.

Based on guidance provided on July 28, 2011. The company is not updating the prior guidance and actual results may differ.

2.

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.

2010-

A

2011-

G

1

Total Product Sales

\$170M

\$247

260M

Xyrem

\$143M

\$215

225M

Luvox CR

\$27M

\$32

35M

SG&A and R&D Combined

\$95M

\$105

110M

GAAP Net Income

\$33M

\$123

131M

Adjusted Net Income

2

\$61M

\$145

153M

GAAP EPS

\$0.83

\$2.68 -

\$2.79

Adjusted EPS

2

\$1.55

\$3.15

\$3.25

19

Investment Rationale

High sales and earnings growth rates

High margins and high operating leverage

Significant potential to increase Xyrem sales

Strong  
Xyrem  
exclusivity  
position  
including  
patents  
extending  
to  
2024

Potential to leverage existing commercial capabilities with new products

Disciplined approach to resource allocation

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

~\$250M cash at closing  
2

Strong balance sheet  
with no debt  
1

Accretion for Jazz Pharmaceuticals shareholders is on a fully-taxed adjusted EPS basis. Adjusted EPS is a non-GAAP financial

2

Pro forma estimate as of Jan 1, 2012.

Compelling Strategic and Financial Benefits

Jazz

Pharmaceuticals plc

Ireland



22

Jazz Pharmaceuticals plc

12 products  
currently marketed in US

>\$475 million

in  
revenues  
in  
first  
12  
months

>\$200 million

in  
cash  
generated  
in  
first  
12  
months

Jazz  
Pharmaceuticals:  
slightly  
under  
80%;  
Azur  
Pharma: slightly over 20%

Combined capitalization approximately 60M shares fully diluted at closing

Jazz  
Pharmaceuticals

board  
represented  
funds  
entered  
into  
voting  
agreements (~43% of shares)

99%  
of  
Azur  
shareholders entered into agreement to take necessary actions

Current directors of Jazz Pharmaceuticals

Seamus Mulligan (Chairman and CEO, Azur Pharma)  
Portfolio & Financial  
Projections  
Ownership in  
Combined Company  
Shareholder Votes  
Board of Directors  
Management

Bruce Cozadd, Chairman and CEO

Kate Falberg, CFO

Seamus Mulligan, Chief Business Officer, International Business Development

Azur executives join JPI executives in leadership roles  
Anticipated Closing: 1Q12



23

Azur Pharma

Compelling Fit With Jazz Pharmaceuticals

\$0

\$20

\$40

\$60

\$80

\$100

2006

2007

2008

2009

2010

CNS

Women's Health

Net Sales

(Millions)

Strong commercial focus and expertise  
in CNS and women's health

Key products present new growth  
opportunities

Lower risk pipeline of line extensions for  
clozapine franchise and LCM programs  
for key women's health brands

24  
2011 Estimated Revenues  
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%



25

Sourcing of new products for all markets

Potential expansion into Europe

Benefits of New Corporate Structure

Access to international capital markets and business development

opportunities

Sales, marketing, and clinical/medical science liaison organizations

Multi-product supply chain management

BD executives with demonstrated success

Enhanced management capabilities

Enhanced ability to attract and retain key talent

Additional locations (Philadelphia, Dublin)

Parent company in Ireland expected to license, develop and acquire existing and new products





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Next Steps

File preliminary proxy  
statement and S-4

Expected to  
close 1Q12

Transaction is  
subject to customary  
closing conditions  
and regulatory  
approvals, including:

SEC effectiveness of S-4

Jazz Pharmaceuticals, Inc.  
stockholder approval

Azur approval of other  
necessary actions

Antitrust clearance

Transaction will be taxable to  
Jazz Pharmaceuticals, Inc.  
stockholders

Jazz Pharmaceuticals plc  
shares to be traded on Nasdaq

27

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

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

~\$250M cash at closing

Strong balance sheet  
with no debt

1

Accretion for Jazz Pharmaceuticals shareholders is on a fully-taxed adjusted EPS basis. Adjusted EPS is a non-GAAP financial

2

Pro forma estimate as of Jan 1, 2012.

Compelling Strategic and Financial Benefits

Jazz

Pharmaceuticals plc

Ireland

1

2







29

FY 2011G

FY 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

Loss on extinguishment of debt

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)

\$123-131

7

14

2

\$145-153

\$2.68-2.79

\$3.15-3.25

46-47

-

(1)

\$33

8

8

2

\$61

\$0.83

\$1.55

39

12

(1)

1.

Based on guidance provided on July 28, 2011. The company is not updating the prior guidance and actual results may differ.

-

1

30  
Xyrem  
(sodium oxybate)  
Boxed Warning  
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).

XYREM (sodium oxybate) PI

!WARNING:

Central  
nervous  
system  
depressant  
with  
abuse  
potential.

Should  
not



be  
used  
with  
alcohol  
or  
other  
CNS  
depressants.

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 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.)

