JAZZ PHARMACEUTICALS INC
Form 425
October 19, 2011

Filed by Azur Pharma Limited

Pursuant to Rule 425 under The Securities Act of 1933

And Deemed Filed Pursuant to Rule 14a-12

Under the Securities Exchange Act of 1934

Subject Company: Jazz Pharmaceuticals, Inc.

Commission File Number: 001-33500

Date: October 19, 2011

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

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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

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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,
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 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

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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
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.

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

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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
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

16
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.
1. National Institute of Mental Health. http://www.nimh.nih.gov/health/publications/the-numbers-count-mental-disorders-in-ar
3. Fireman B, et al. Am J Psychiatry. 2001;158:1904-1910. 4. Grabill K et al..Assessment of obsessive-compulsive disorder: a
1999:600-610. 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

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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

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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 financia
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

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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

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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

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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 financia
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.)