

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,

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

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=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
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

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 measure.
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

26

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.)

