JAZZ PHARMACEUTICALS INC
Form 425
September 21, 2011

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Filing by: Jazz Pharmaceuticals, Inc.

Subject Company: Jazz Pharmaceuticals, Inc.

SEC File No. of Jazz Pharmaceuticals, Inc.: 001-33500

The following includes the slides and transcript of an investor presentation made on Tuesday, September 20, 2011 at the UBS Global Life Sciences Conference by Bruce Cozadd, Chairman and Chief Executive Officer of Jazz Pharmaceuticals, Inc. (Jazz Pharmaceuticals). Both the slides and transcript contain 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 Securities and Exchange Commission (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.

Additional Information and Where to Find It

In connection with the proposed transaction, 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 IMPORTANT INFORMATION ABOUT JAZZ PHARMACEUTICALS, AZUR PHARMA AND THE PROPOSED TRANSACTION. Investors 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.

Bruce Cozadd
Chief Executive Officer
September 20, 2011
UBS Global Life Sciences Conference

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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

Additional Information and Where to Find It

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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.

4
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

Strategic Transaction with
Azur Pharma

6
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

7
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

8
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)

Lower risk pipeline of line extensions for
clozapine franchise and LCM programs
for key women s health brands
Azur Pharma
Compelling Fit With Jazz Pharmaceuticals
$0
$20
$40
$60
$80
$100
2006
2007
2008
2009
2010

9
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%

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
10
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

10% prescription share despite largely generic clozapine market

FazaClo High Dose (HD) launched September 2010

More than 20% switched from Low Dose (LD) as of 2Q11

Dosing flexibility and lower pill burden

Generics filed to FazaClo
settlement with Teva with potential launch of lower dosage
product in 2Q12 and higher dosage in 2015

Additional clozapine line extensions in development
11
1. See full prescribing information on website

CONFIDENTIAL
12
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

Diversified
and
balanced
set
of
six
products
with
2010
net
sales
of
$27M

Significant
growth
opportunity
driven
by
Elestrin
,
a
topical
gel
ERT
therapy

Patents through 2022

Revamped Elestrin promotion model in 2010 leveraging 51 sales representatives
1
1

Current Business and Financial
Overview

Xyrem -
Strong Sales Growth
2010 Xyrem Sales $143M
2011 Guidance $215M-$225M
$0
$10
$20

$30
$40
$50
$60
$43
$34
$37
$43
$56
1Q11
4Q10
3Q10
2Q10
2Q11
12%
8%
8%
6%
YOY Volume
Growth
11%
1
1.
Based on guidance provided on July 28, 2011. The company is not updating the prior guidance and actual results may differ.

Xyrem is a Standard of Care in Narcolepsy

Only FDA-approved product for both cataplexy and excessive daytime sleepiness in patients with narcolepsy

Marketed in U.S. since 2002

Marketed in major European countries by
UCB and in Canada by Valeant

Currently used in ~8,700 U.S. patients, usually in conjunction with stimulant therapy

Distributed
under
proprietary
Xyrem
Success
Program
®

The Burden of Narcolepsy

Affects 1 in 2000 in US
1

multiple sclerosis and Parkinson's disease
2

> cystic fibrosis
3

Although narcolepsy is thought to affect between
125,000 and 200,000 Americans, only about 50,000
are
diagnosed
4

Key symptoms can be debilitating

Cataplexy occurs in 60%-100% of patients

100% experience excessive daytime sleepiness

1.
National Institute of Neurological Disorders and Stroke. http://www.ninds.nih.gov/disorders/narcolepsy/detail_narcolepsy.htm
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.

-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
1
Week 2
Week 4
Baseline
Reduction in Weekly
Cataplexy Attacks
-28%
-49%*
-69%+
*p<0.001 vs placebo
*p<0.05 vs placebo
+p<0.005 vs placebo
1.
Trial 3: From a 8-week, multicenter, randomized, double-blind, placebo controlled, parallel-arm trial of narcolepsy patients (N
withdrawn prior to randomization, and stimulants were continued throughout the study at stable doses. In XYREM clinical tria
80% of patients maintained concomitant stimulant use. XYREM International
Study Group. *J Clin Sleep Med*. 2005;1:391.
2.
Trial 1: From a 4-week, double-blind, placebo-controlled trial of narcolepsy patients (N=136) with moderate to severe cataplex
administered sodium oxybate with placebo for the treatment of narcolepsy. Patients continued to receive stable stimulant therap
2002;25(1):42-29.
2

Most Common Adverse Events in Controlled Studies of Xyrem

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

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

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

Strong Sodium Oxybate Patent Coverage
* Listed in FDA Orange Book
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

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
July
2011.
79%
8%
3%
1%
9%
Commercial
Medicaid
Medicare Part D
Patient
Asst
Program
Cash

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

2011 Guidance Reflects High Operating Leverage
2010-
A
2011-
G
1
Total Product Sales

Xyrem
Luvox CR
SG&A and R&D Combined
GAAP Net Income
Adjusted Net Income
2
GAAP EPS
Adjusted EPS
2
$170M
$143M
$27M
$95M
$33M
$61M
$0.83
$1.55
$247
260M
$215
225M
$32
35M
$105
110M
$123
131M
$145
153M
$2.68 -
$2.79
$3.15
$3.25
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 E
A reconciliation of adjusted net income to GAAP net income and the related per share amounts is in a table included with this

23
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

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.
-
FY 2011G
1

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.

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
FazaClo (clozapine)PI
ORTHOSTATIC HYPOTENSION, WITH OR WITHOUT SYNCOPE, CAN OCCUR WITH CLOZAPINE TREATMENT.
COLLAPSE CAN BE PROFOUND AND BE ACCOMPANIED BY RESPIRATORY AND/OR CARDIAC ARREST. ORTH
HYPOTENSION IS MORE LIKELY TO OCCUR DURING INITIAL TITRATION IN ASSOCIATION WITH RAPID DOSE

PATIENTS WHO HAVE HAD EVEN A BRIEF INTERVAL OFF CLOZAPINE (ie, 2 OR MORE DAYS SINCE THE LAST
TREATMENT SHOULD BE STARTED WITH 12.5 MG ONCE OR TWICE DAILY. (SEE WARNINGS AND DOSAGE A
ADMINISTRATION.) SINCE COLLAPSE, RESPIRATORY ARREST, AND CARDIAC ARREST DURING INITIAL TRE
OCCURRED IN PATIENTS WHO WERE BEING ADMINISTERED BENZODIAZEPINES OR OTHER PSYCHOTROPIC
CAUTION IS ADVISED WHEN CLOZAPINE IS INITIATED IN PATIENTS TAKING A BENZODIAZEPINE OR ANY O
PSYCHOTROPIC DRUG. (SEE WARNINGS.)
ELDERLY PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS TREATED WITH ANTIPSYCHOTIC DRUGS ARE A
RISK OF DEATH. ANALYSES OF SEVENTEEN PLACEBO-CONTROLLED TRIALS (MODAL DURATION OF 10 WE
IN PATIENTS TAKING ATYPICAL ANTIPSYCHOTIC DRUGS, REVEALED A RISK OF DEATH IN DRUG-TREATED
BETWEEN 1.6 TO 1.7 TIMES THE RISK OF DEATH IN PLACEBO-TREATED PATIENTS. OVER THE COURSE OF A
WEEK CONTROLLED TRIAL, THE RATE OF DEATH IN DRUG-TREATED PATIENTS WAS ABOUT 4.5%, COMPAR
OF ABOUT 2.6% IN THE PLACEBO GROUP. ALTHOUGH THE CAUSES OF DEATH WERE VARIED, MOST OF THE
APPEARED TO BE EITHER CARDIOVASCULAR (eg, HEART FAILURE, SUDDEN DEATH) OR INFECTIOUS (eg, PN
NATURE. OBSERVATIONAL STUDIES SUGGEST THAT, SIMILAR TO ATYPICAL ANTIPSYCHOTIC DRUGS, TRE
CONVENTIONAL ANTIPSYCHOTIC DRUGS MAY INCREASE MORTALITY. THE EXTENT TO WHICH THE FIND
INCREASED MORTALITY IN OBSERVATIONAL STUDIES MAY BE ATTRIBUTED TO THE ANTIPSYCHOTIC DRU
TO SOME CHARACTERISTIC(S) OF THE PATIENTS IS NOT CLEAR. FAZACLO® (clozapine, USP) IS NOT APPROV
TREATMENT OF PATIENTS WITH DEMENTIA-RELATED PSYCHOSIS. (SEE WARNINGS.)

4.
OTHER
ADVERSE
CARDIOVASCULAR
AND
RESPIRATORY
EFFECTS

5.
INCREASED
MORTALITY
IN
ELDERLY
PATIENTS
WITH
DEMENTIARELATED
PSYCHOSIS

Transcript

Jazz Pharmaceuticals, Inc.

September 20, 2011

9:30 AM ET

Ami Fadia: Hello. Thanks for joining us. The next presentation is from Jazz Pharmaceuticals. I m Ami Fadia, the (inaudible) tech pharma analyst at UBS and it s my pleasure to invite Bruce Cozadd, the CEO at Jazz. Following the presentation we ll have a breakout session at the Broadway Room. Thanks.

BruceCozadd:

Good morning, everyone. Thank you, Ami, and UBS for the opportunity to present this morning. I m particularly pleased to have the opportunity to present this morning as we announced an important transaction yesterday and this will be a good chance to give all of you an update on that.

Before I get into the presentation, let me remind you, as always, that we ll make some forward-looking statements during this presentation. Those are subject to the occurrence of a number of risk factors that you can read about in our SEC filings. And in this case, those risk factors also include risk factors related to our potential transaction, including timing, closing and integration. And since we are between announcement and closing of a transaction, I ll also point you to the SEC website for a series of filings that we and our partner will make over the coming months. Please see those filings for additional information.

Well, before I get to the transaction, let me remind you of the strategy we ve been talking about now for the past year, a strategy that I think makes sense for the Company and explains our interest in this transaction. The core of our strategy has been, and remains, to build on our success with Xyrem. Xyrem is our lead product and we believe it still offers substantial growth potential in narcolepsy. And the core to our strategy remains optimizing the value of that franchise.

The second pillar of our strategy is building on our strong commercial business and our strong commercial infrastructure by adding additional on-market or near-market products.

The third element of our strategy is, over time, to build and sustain a pipeline of smart R&D investments; investments in R&D programs that are a good fit with our specialty commercial focus, products that are differentiated and can be sold to a concentrated group of physicians that can be reached effectively with our sales force. As part of this strategy, we are currently recruiting for a head of R&D who will help lead these efforts.

And all of these strategic priorities are built over a base, which is our culture, our entrepreneurial ownership-based culture of the Company. And that means making smart resource allocation decisions across these elements of our strategy; smart investments in continuing to grow and defend the Xyrem franchise, smart investments in new products and smart investments in R&D.

So, the transaction we announced yesterday is a merger with Azur Pharma. And let me tell you why we think this transaction makes so much sense. First of all, it provides us an expanded group of products, a more diversified CNS and women s health revenue line. It

provides us with increased scale and a platform for future growth. Part of doing this transaction was not to look at what one transaction makes sense, but to set ourselves up to be able to do additional transactions in the future. It gives us a stronger base on which to execute our R&D strategy. And with the entire management team of Azur Pharma coming over to join the combined company, I think it will strengthen our management team.

On the financial side, this transaction is expected to be accretive to our adjusted after-tax EPS. And we have given some forward-looking statements here about expecting over $475 million in revenue and $200 million in cash flow in the first 12 months of combined operations. The company should have $0.25 billion in cash at closing, a very strong balance sheet and no debt.

A couple words about the transaction itself. This transaction will be effected in such a way that the Jazz Pharmaceuticals, Inc. shareholders will own just less than 80% and the Azur Pharma shareholders will own just more than 20% of the combined Jazz Pharmaceuticals plc, which will based in Ireland.

In terms of shareholder votes that are required, we do have voting agreements in place with virtually all of the Azur shareholders and 43% of the Jazz shareholders. The Board of Directors will be comprised of our current Board, with the addition of Seamus Mulligan, the Chairman and CEO of Azur. The management team will include all of the current Jazz and Azur management teams, including myself, Kate Falberg, our CFO who s with me here today, Seamus, and other key members of the Azur team, including Eunan Maguire, David Brabazon, Fintan Keegan and Mike Kelly. We anticipate closing in the first quarter.

In addition to the portfolio of products, Azur brings us strong expertise in CNS and women s health. Their approximately 170 employees are split among three US sales forces in pain, psychiatry and women s health. That comprises 105 of their employees, as well as a strong medical affairs team and a relatively lean home office split among Dublin and Philadelphia. They also do have a lower-risk development pipeline, including some lifecycle management programs.

On the right-hand side you see their net sales growth, which reached over $80 million in 2010. We re forecasting for 2011 sales in the $95 million to $100 million range. That s with a gross margin of 80% to 85% and expected EBITDA of $27 million to $31 million.

When you add those revenues to our already given guidance for Jazz Pharmaceuticals revenues, you see on the right how those revenues would split among the Jazz and Azur products. You can see that Xyrem will remain a significant driver of the overall Company s performance.

Let s talk about a couple of the key Azur products, starting with Prialt for chronic pain. This product had sales in 2010 of approximately $20 million, though Azur did not have the product for the entire year, acquiring it in May. This is a formulation of the synthetic peptides aconitine in an intrathecal pump. And we see this product as similar to Xyrem in many ways. It certainly requires a high-touch sales capability with a heavy clinical emphasis. Like Xyrem, we think there s substantial room for growth with the product currently representing less than 3% of the available pain market pumps. And we see it as having a long franchise life due to intellectual property and other protection. Azur does have worldwide rights to this product, with European rights licensed to Eisai.

The next product is FazaClo with 2010 sales of $37 million. This is an orally disintegrated clozapine tablet approved for the management of treatment-resistant schizophrenic. The product has achieved a 10% prescription share, despite the fact that it

competes in a large genericized clozapine market. Azur did launch a higher-dose version of FazaClo about a year ago and has switched over 20% from their lower dose strengths through the first half of this year. Doctors tell the company they appreciate the dosing flexibility and lower pill burden for patients due to the higher-dosage strengths.

There are generic filers against FazaClo. In a recent settlement with Teva, it would allow for a launch of the lower dosage form in mid-2012 and the higher dosage form in 2015. Azur does have two different formulations of clozapine in its pipeline.

Turning to the women s health business, which is comprised of a number of different brands, there were two 2010 sales of about $27 million with growth led by Elestrin, a topical gel ERT therapy with long patent life and a new promotional model.

Okay. Let me now spend a few minutes on the Jazz Pharmaceuticals base business and give you an update on that; starting, of course, with Xyrem. Xyrem s been experiencing terrific growth. You see here our recently announced second quarter results of $56 million in net sales. We gave guidance at the end of our on our second quarter call at the end of July of $215 million to $225 million for 2011. And you can see that part of the reason for that growth is the improving volume growth of the product, where we ve seen an acceleration in that volume growth with double-digit year-over-year volume growth in each of the last two quarters. I ll also point out that we did recently take a price increase on Xyrem of just over 19% on September 1st.

Xyrem is the only FDA-approved product for the treatment of two major symptoms of narcolepsy, cataplexy and excessive daytime sleepiness. It s been on the market since 2002 and is marketed ex-US by our partners, UCB in Europe and Valeant in Canada. It s currently used in about 8,700 patients, often in combination with stimulant therapy, often Provigil or Nuvigil. And it s distributed under a very tightly controlled REMS called our Xyrem Success Program.

If we think about narcolepsy, this is an orphan condition and very debilitating for the patients. Although it s estimated that narcolepsy affects 125,000 to 200,000 patients in the United States, we believe only 50,000 of those patients are diagnosed and treated. The key symptoms are cataplexy, which is a sudden loss in muscle tone associated with an emotional stimulus. This can be a slight sagging of your face or loss of all muscle control and collapsing to the ground.

Excessive daytime sleepiness is present in all narcolepsy patients. This is not just being tired as you sit through another boring presentation at an investor conference. This is a real inability to go through your day without feeling the sudden need and the irresistible urge to take naps. People with severe, excessive daytime sleepiness really have a tough time holding down a job or maintaining relationships.

If we look at how Xyrem affects these two key symptoms, on the left we see a trial where we showed improvement in excessive daytime sleepiness. It s measured by the Epworth Sleepiness Scale. And it s important to note in this trial patients could be on stimulant therapy throughout the trial. So, you re really looking here at benefit above and beyond benefits you would get from stimulant therapy.

On the right-hand side we look at the effect on cataplexy, measuring the weekly number of cataplexy episodes with the 9 gram dose of Xyrem, providing a 69% median reduction in cataplexy attacks. So, what we see from this slide is that Xyrem is very effective in treating the two key symptoms of narcolepsy.

On the AE side there are a number of AEs associated with Xyrem use, the most common of which include nausea, dizziness and headache. There is a black box warning for

Xyrem. It is a CNS depressant and should not be used in combination with alcohol or other CNS depressants. The black box warning for Xyrem, as well as the other products with black box warnings, are included on the product websites. And if you go to our website and look at a copy of this presentation, you ll find them there as well.

We have very strong IP protection covering Xyrem with nine patents, seven of which are Orange Book listed. A number of these patents relate specifically to the restricted distribution system and we believe provide very unique protection for the product. You ll see a number of those patents have issued in the past two years. So, you should know that we remain committed to aggressively pursuing and defending intellectual property protection for Xyrem.

Xyrem enjoys a very strong reimbursement coverage with relatively low rates of prior authorizations required, and with the majority of our patients having monthly out-of-pocket costs of less than $50. On the right you see the make-up of the payers for the product. And I will point out that we distribute a fair amount of product free of charge to patients who can t afford it.

As we talk about the opportunity to continue growing Xyrem, we ve launched a number of initiatives designed to improve our market penetration over time, taking us up from those 8,700 out of 50,000 diagnosed patients who currently are on Xyrem treatment. Our new initiatives include adding additional physician targets for our sales force, physicians that we know are treating narcolepsy and prescribing stimulants, but who had not been called on previously by our sales force. By improving the education we provide through the REMS, making sure that physicians and our pharmacy are doing a good job of educating patients about the safe use of the product and what to expect when initiating therapy.

We have a number of other patient services that have been rolled out, including more contact with nurses, including a welcome call and frequent calls during the period when they re initiating therapy. Also, a brand new patient mentoring program, giving new Xyrem patients the chance to talk to other patients who ve had experience with Xyrem. These are volunteers who are not paid for their services. And we also have a number of patient assistance programs in place designed to make sure that Xyrem is available to patients who need it, not patients who can afford it.

Let me wrap up the discussion of our business with a look at our guidance for 2011. Again, this guidance is current as of the end of July. We re not updating it today.

You can see that we re projecting very strong top line growth with guidance this year of sales between $247 million and $260 million. That represents approximately a 50% to a 60% increase in sales. And given the relatively modest growth in spending at the Company, we see tremendous earnings leverage in our model. That 50% to 60% top line growth is reflected in a more than doubling of our adjusted EPS. You see here adjusted net income guidance of $145 million to $153 million and adjusted EPS guidance of $3.15 to $3.25. We do provide a reconciliation of adjusted net and adjusted EPS back to GAAP figures, again, in an appendix to this presentation.

So, let me conclude by just reiterating my enthusiasm for the transaction we announced yesterday. We believe the merger with Azur provides compelling strategic, commercial, organizational and financial benefits for our company, positions us very well to achieve our vision to help more patients and to continue to build shareholder value. Thank you very much.

And I believe we have a Q&A in a separate room starting soon, the Broadway Room. Thank you.