COWEN AND COMPANY

Quick Take

Johnson & Johnson — Outperform (1)

JNJ: $70.60

Quick Take: Zytiga Gets FDA OK For Use In Pre-Chemo Setting On rPFS Data

December 11, 2012

Analysts

Josh Jennings, M.D.
(646) 562-1333
josh.jennings
@cowen.com

Christopher Hamblett, Ph.D.
(617) 946-3950
chris.hamblett
@cowen.com

Denis Kelleher
(646) 562-1389
denis.kelleher
@cowen.com

Yesterday afternoon, the FDA approved Zytiga (abiraterone acetate) for use in treating men with metastatic castration-resistance prostate cancer prior to receiving chemotherapy. The approval in the pre-chemo setting was based on Phase III data that showed a statistically significant improvement in radiographic progression-free survival (rPFS) in patients receiving Zytiga plus prednisone compared to the placebo plus prednisone (HR=0.43; <0.0001). Zytiga failed to achieve statistical significance on the pre-specified overall survival endpoint (p=0.0097 vs the pre-specified p-value of p=0.0008) in this setting, but we expected the drug to be approved on the rPFS data and strong hazard ratio for overall survival (HR = 0.75; 95% CI = [0.61, 0.93]; p=0.0097). Median overall survival data in chemotherapy naïve patients receiving Zytiga was 35.3 months compared to 30.1 months in patients receiving placebo plus prednisone, a net improvement of 5.2 months. We view Zytiga's label expansion based on rPFS data as a positive for JNJ.

The approval comes a few days ahead of its scheduled mid-December PDUFA date. The pre-chemo CRPC market opportunity is estimated to be approximately three times the size of the post-chemo CRPC opportunity. Our global Zytiga sales estimates of $975MM in 2012, $1,120MM (+15%) in 2013, $1,165MM (+4%) in 2014, $1,220MM (+5%) in 2015, $1,300MM (+7%) in 2016, and $1,380MM (+6%) in 2017 assume competitive pressures from Medivation's Xtandi (enzalutamide) and assume Xtandi achieves regulatory approvals in both settings as well.

Phase III interim data for Medivation/Astellas' androgen receptor antagonist Xtandi in chemotherapy-naive prostate cancer are expected in 2013. Xtandi was approved for use in post-chemo CRPC patients in September 2012. Xtandi acts similarly to Zytiga and has roughly equivalent efficacy (based on overall survival data in the post-chemo setting), but offers potential convenience and tolerability advantages over Zytiga in being administered without prednisone. However, prior to today's label expansion, Zytiga had already gained off-label use in the pre-chemo setting (likely among Medical Oncologists), which supports our clinical consultants' views that co-administration with prednisone, while perceived as a potential disadvantage, is not a major barrier to Zytiga's use.

Addendum

STOCKS MENTIONED IN IMPORTANT DISCLOSURES

Ticker	Company Name
JNJ	Johnson & Johnson

ANALYST CERTIFICATION

Each author of this research report hereby certifies that (i) the views expressed in the research report accurately reflect his or her personal views about any and all of the subject securities or issuers, and (ii) no part of his or her compensation was, is, or will be related, directly or indirectly, to the specific recommendations or views expressed in this report.

IMPORTANT DISCLOSURES

Cowen and Company, LLC and or its affiliates make a market in the stock of JNJ securities.

Cowen and Company, LLC compensates research analysts for activities and services intended to benefit the firm's investor clients. Individual compensation determinations for research analysts, including the author(s) of this report, are based on a variety of factors, including the overall profitability of the firm and the total revenue derived from all sources, including revenues from investment banking. Cowen and Company, LLC does not compensate research analysts based on specific investment banking transactions.

DISCLAIMER

This research is for our clients only. Our research is disseminated primarily electronically and, in some cases, in printed form. Research distributed electronically is available simultaneously to all Cowen and Company, LLC clients. All published research, including required disclosures, can be obtained on the Firm's client website, www.cowenresearch.com.

Further information on any of the above securities may be obtained from our offices. This report is published solely for information purposes, and is not to be construed as an offer to sell or the solicitation of an offer to buy any security in any state where such an offer or solicitation would be illegal. Other than disclosures relating to Cowen and Company, LLC, the information herein is based on sources we believe to be reliable but is not guaranteed by us and does not purport to be a complete statement or summary of the available data. Any opinions expressed herein are statements of our judgment on this date and are subject to change without notice.

Notice to UK Investors: This publication is produced by Cowen and Company, LLC, which is regulated in the United States by FINRA and is disseminated in the United Kingdom by Cowen International Limited ("CIL"). In the United Kingdom, 'Cowen and Company' is a Trading Name of CIL. It is communicated only to persons of a kind described in Articles 19 and 49 of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005. It must not be further transmitted to any other person without the consent of CIL.

COWEN AND COMPANY RATING DEFINITIONS (a)

Rating	Definition
Outperform (1)	Stock expected to outperform the S&P 500
Neutral (2)	Stock expected to perform in line with the S&P 500
Underperform (3)	Stock expected to underperform the S&P 500

(a) Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period.

COWEN AND COMPANY RATING ALLOCATION (a)

Rating	Pct of companies under coverage with this rating	Pct for which Investment Banking services have been provided within the past 12 months
Buy (b)	55.7%	9.2%
Hold (c)	41.9%	1.7%
Sell (d)	2.4%	0.0%

(a) As of 09/30/2012. (b) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's rating definitions (see above). (c) Corresponds to "Neutral" as defined in Cowen and Company, LLC's ratings definitions (see above). (d) Corresponds to "Underperform" as defined in Cowen and Company, LLC's ratings definitions (see above). Note: "Buy," "Hold" and "Sell" are not terms that Cowen and Company, LLC uses in its ratings system and should not be construed as investment options. Rather, these ratings terms are used illustratively to comply with NASD and NYSE regulations.