August 9, 2013

Brian Marckx, CFA
bmarckx@zacks.com
Ph (312) 265-9474

Zacks Small-Cap Research

scr.zacks.com

111 North Canal Street, Chicago, IL 60606

Chembio Diagnostics Inc. (CEMI- NASDAQ)

CEMI: Soft Q2 But Look For Rebound in Q3

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/14/2010
Current Price (08/08/13)	$4.19
Target Price	**$9.00**

OUTLOOK

Lateral flow sales helping buoy revenue. Alere taking market share in the U.S. and recent recommendations on HIV testing should aid U.S. sales. Alere launching competing product, however, the potential effects of which we will be watching. Int'l lateral flow sales have been very strong but can be variable q-to-q. CEMI is focused on growing this business - fruits of which are already being seen - with more expected as "new opportunities" appear to be on the horizon. DPP sales ex-Brazil could also accelerate. These should help offset a bigger and earlier than anticipated decline in FIOCRUZ sales.

Pipeline progress continues and was highlighted by FDA approval of DPP HIV test in December. U.S. launch could happen in early-2014 which will be a very meaningful milestone. Syphilis test and HIV/syphilis combo test are also in the pipeline, as is a potentially pursuit of OTC approval of the company's (blood sample) lateral flow test.

Cash position and the balance sheet remain very healthy.

We are maintaining our Outperform rating.

SUMMARY DATA

52-Week High	**$5.71**
52-Week Low	**$4.05**
One-Year Return (%)	**-15.66**
Beta	**0.54**
Average Daily Volume (sh)	**32,399**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$39**
Short Interest Ratio (days)	**3.92**
Institutional Ownership (%)	**17**
Insider Ownership (%)	**17**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**22.8**
Earnings Per Share (%)	**-4.8**
Dividend (%)	**N/A**
P/E using TTM EPS	**24.6**
P/E using 2013 Estimate	**34.9**
P/E using 2014 Estimate	**15.0**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Blend**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue
(millions)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	$6.65 A	$6.08 A	$5.01 A	$7.87 A	$25.61 A
2013	$6.68 A	$5.39 A	$9.19 E	$6.48 E	$27.75 E
2014					$33.19 E
2015					$31.71 E

Adjusted Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	$0.08 A	$0.06 A	-$0.06 A	$0.08 A	$0.17 A
2013	$0.05 E	-$0.04 A	$0.06 E	$0.04 E	$0.12 E
2014					$0.28 E
2015					$0.34 E

Zacks Projected EPS Growth Rate - Next 4 Years % **24**

© Copyright 2013, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Q2 2013

Q2 2013 revenue of $5.4 million fell 11% yoy and was well below our $6.4 million forecast. DPP sales fell $1.5 million accounting for all (and more) of the yoy decline and miss relative to our estimate. This was partially offset, however, by relative strength in lateral flow sales. Lateral flow sales increased about 32% yoy and were about $100k better than our $4.0 million estimate. As Chembio announced in June, they received a $5.3 million purchase order from an international procurement agency for one of their lateral flow products - only $869k of that was recognized in Q2 and we expect to see most of the remainder of that to be accounted for in Q3. Meanwhile, non-product revenue remains largely in-line with our estimates ($332k A vs $386k E).

Gross margin at 42.3% was slightly better than our 41.3% estimate - likely due to (relatively lower margin international) DPP sales coming in much lower than our estimate ($695k A vs. $1.8MM E). Q2 operating expenses were $2.7 million, moderately higher than our $2.4 million estimate as a result of additional R&D expense related to the DPP HIV CLIA waiver.

EPS
We use adjusted net income and EPS for consistency purposes. As a reminder, in Q4 2011 CEMI took a non-cash gain of $5.16 million to income from the reversal of deferred tax asset as they expected to generate positive pre-tax income from that point forward. Their GAAP income tax rate of ~39.7% is 90% non-cash until they exhaust (which, based on our current model will occur sometime in 2015) their entire deferred tax asset which stood at $4.2 million at the end of Q2. Q2 adjusted net income and EPS of approximately ($358)k and ($0.04) compared to our $294k and $0.03 estimates.

Cash
Excluding changes in working capital, cash from operations was an outflow of $133k. CEMI exited Q2 with $8.7 million in cash and equivalents and no debt. CEMI also has a $2.0 million credit line (untapped at Q2 quarter-end).

Business / Pipeline Update

DPP HIV, U.S.
FDA approval for all sample types (oral fluid, whole blood, serum, and plasma) came in December. Studies to support CLIA waiver started in April. CEMI had hoped to have an FDA submission for CLIA waiver by July but this is now pushed back to Q4 2013. CLIA waiver could come in Q1 2014, with launch potentially happening shortly afterwards.

In clinical studies the product has shown to have superior performance to OraSure's oral fluid test as well as other rapid HIV tests using blood samples. CEMI's DPP HIV test's FDA approved label includes claims of sensitivity/specificity on oral fluid and whole blood of 98.9%/99.9% and 99.9%/100%, respectively. Oral fluid sensitivity was 100% among patients not on anti-retroviral medication.

Certain advantages of CEMI's DPP HIV product, including superior performance, long shelf-life, broader label including approved for patients 2 years and older (versus 13 yrs and older with competitors'), and earlier detection on serum samples should bode well for it competing against OraSure's oral fluid rapid HIV test. CEMI's plan for selling the test includes detailing to the public health sector with its own (very small) sales force as well as through distributors to target hospitals and physicians' offices. We model the test to launch in 2014.

DPP Syphilis Screen and Confirm
Syphilis Screen and Confirm (treponemal / non-treponemal) test was CE Marked in Europe in early October 2011. CEMI noted that during Q2 they established distribution for the test in the U.K.

Relative to the road to FDA approval, CEMI believes the data they have, which includes data from a multi-site study done in China with over 3,000 samples and published late last year online in the journal Clinical Infectious Diseases (link: http://cid.oxfordjournals.org/content/early/2012/10/29/cid.cis928.abstract) provides significant support to reinitiate clinical trials in their quest to gain 510(k) clearance from the FDA. CEMI submitted the additional data to the FDA and the regulator responded in February. While CEMI believes they have what they need to pursue trials, in August they noted that they have a supply issue for a key raw material and until that issue is resolved, the studies

will be on hold. Prior to this issue CEMI had hoped to commence the studies in April or May, submit the 510(k) application by end of Q3 and have FDA clearance by mid-2014. Obviously that timeline will now not happen.

As a reminder, CEMI had previously announced that they have already identified 3 study sites and drafted contracts related to the studies - so at least some of the early leg-work seems to be done.

We think CEMI's DPP POC syphilis screen and confirm test could have significant appeal given that it would be the first POC treponemal/non-treponemal test on the market with accuracy competitive to lab tests. The test would potentially draw significant demand overseas as well, particularly in developing countries where infectious diseases (including HIV and syphilis) can be overly problematic.

DPP HCV

Chembio is now even more focused on development of a competitive DPP hepatitis C test following the recently released draft recommendation by the CDC that all Americans ages 45 - 65 be tested for the virus as well as independent data published in the Journal of Virology which indicated relatively high accuracy of CEMI's HCV test.

Chembio efforts relative to DPP HCV have most recently focused on improving upon accuracy and competitiveness compared to rapid HCV tests already on the market. Chembio is now looking at including antigen detection on top of antibody detection. All the rapid HCV tests currently on the U.S. market are all antibody tests, which can fail to detect the virus especially in the early stages of the disease when antibody presence is low.

In Q3 2012 CEMI completed an initial feasibility study on proprietary antigens and had been awaiting additional proprietary materials to further improve the performance of their initial DPP HCV test (the initial test was used in the study cited in The Journal of Virology article) compared to competitive products. CEMI has since received these and is continuing with development of the test.

Assuming development continues with positive results, CEMI believes clinical trials could commence in mid-2014 with potential commercialization in early 2016.

We note that we had removed a DPP HCV test from our model in early 2011 when it looked like CEMI may abandon the program. While we still do not model the test, we will revisit this depending on how things progress.

DPP Syphilis / HIV Combo

CEMI still looking at opportunities in international markets for the test including donor-funded pre-natal testing programs in emerging markets aimed at mother to child transmission. CEMI has submitted the test to the CDC and the World Health Organization accepted it for prequalification in their global procurement scheme. Approvals are expected by end of 2013.

Relative to the FDA approval pathway, CEMI submitted a guidance request to the FDA to determine the appropriate regulatory pathway. FDA recently responded that PMA pathway would be required - as opposed to the quicker 510(k) - which now pushes back anticipated approval and launch timelines by about 6 - 9 months. CEMI will also seek CLIA waiver for the test. We now think the test could launch sometime in mid to late 2015.

OTC HIV

CEMI had been waiting for FDA's decision on OraSure's OTC HIV test before going full-bore on their OTC HIV program. In early July the FDA approved OraSure's OraQuick over-the-counter rapid HIV. The test, which uses an oral swab (saliva) as the sample and is basically identical to the test sold to the clinical market, is the first HIV test to be approved for home use.

FDA's decision essentially green-lighted CEMI's move to proceed with their home-use HIV test. Chembio continues to evaluate the OTC market size and opportunity and will proceed cautiously before committing to expensive clinical trials to gain OTC approval of their Sure Check rapid HIV test, which is already FDA approved for the clinical market. The design, scope, size and cost of CEMI's OTC program are yet to be nailed down but Chembio has almost certainly reviewed the path that OraSure already paved and can use that as (at least) a rough guide for what to expect to gain FDA approval. They will also have the advantage of seeing exactly how well OSUR's test sells and the demand for OTC HIV testing.

Chembio completed the self-testing study required for an IDE submittal but it now in sort of a holding pattern and waiting for more history on how OSUR's test does in the market before committing to further development. If CEMI does go ahead and has an IDE granted, CEMI can then work towards their clinical trials. This would initially involve phase II observed clinical studies followed by a pivotal trial.

It's difficult to gauge the scope of the development program that CEMI will need to follow but for reference, OraSure enrolled ~5,800 people in its pivotal clinical trial. We think it's probably safe to assume that this will be a multi-year and multi-million dollar endeavor. As it is now, we assume FDA approval will not happen prior to the out-year (2015) of our model. CEMI may also look to partner - we will update our assumptions as necessary.

We think, if and when Chembio gets regulatory approval for and launches their OTC HIV test, it can be very competitive to OraSure's OTC test, particularly on performance. We also note that FDA approved OSUR's OraQuick OTC test, despite seemingly low (~92%) sensitivity when administered by consumers (as opposed to by doctors). This low sensitivity is likely in CEMI's sights and we think that if they can show better performance, that would be a very compelling message when the product rolls out. We do note that OSUR's test uses an oral swab as the sample, whereby CEMI's current Sure Check uses blood. Assuming equal performance, oral swab would be considered an advantage from an ease and comfort of administration basis - but this advantage could be potentially largely negated with superior performance. For obvious reasons, FDA and physicians (and consumers) have serious concerns relative to accuracy of HIV home tests - oral swab versus blood sampling may be a relatively benign convenience gap if CEMI's test shows greater accuracy.

DPP HIV Multiplex P24 Antigen / Antibody

CEMI continues to look to leverage the mutliplexing capability of the DPP technology and is now in the early development stages of a DPP HIV P24 Antigen / Antibody test. The potential advantage over their other HIV tests is this mutliplex test would be capable of identifying acute (P24 antigen) as well as chronic (antibody) HIV infection, potentially allowing for diagnosis at an earlier state of infection. Alere has a P24 antigen test which is sold ex-U.S., although performance of the test has been questionable, namely observations of poor sensitivity (64% in one small study, for example). As such, P24 antigen testing in the U.S. is mostly relegated to clinical lab assays. A better performing rapid P24 antigen / antibody multiplex test would likely draw significant demand in the U.S. and elsewhere - which potentially offers CEMI an attractive opportunity with their DPP technology. Progress of development will be something to keep our eye on.

OUR OUTLOOK

Revenue

We now look for 2013 revenue of $27.7 million, reduced from $29.4 million prior to Q2. The reduction reflects the softer than anticipated DPP sales in Q2. While we model a rebound in DPP sales in the coming quarters, we have trimmed our full-year DPP revenue estimate (again, reflecting the miss in Q2). We also note that while we have not materially changed our U.S. lateral flow sales for the current year, we have made some downward adjustments to our out-years for these products as a result of the recent announcement that Alere (CEMI's distributor) is launching a competing product. We look for Q3 total revenue to show a very substantial rebound from Q2, mostly reflecting the remainder of revenue from the $5.3MM international lateral flow P.O.

Net Income / EPS

We now model adjusted net income and EPS of $1.2 million and $0.12 in 2013, compared to $1.4 million and $0.17 in 2012.

RECOMMENDATION / VALUATION

We continue to believe that CEMI trades significantly cheaper than warranted. We value CEMI using 3.5x our estimated 2013 revenue which values the company at approximately $9.00/share. We are maintaining our Outperform rating.

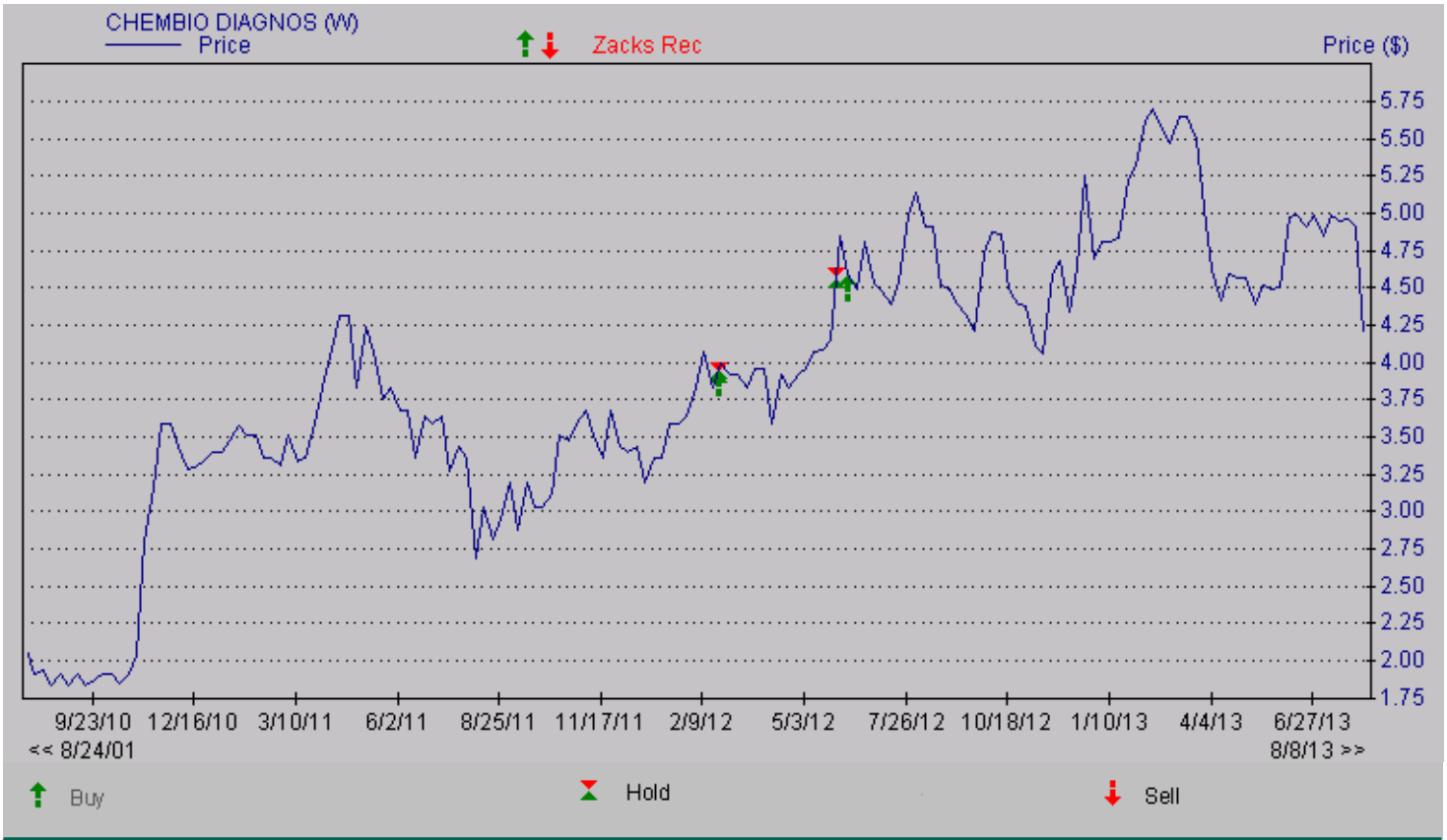
INCOME STATEMENT

Chembio Diagnostics, Inc.

	2012 A	Q1A	Q2A	Q3E	Q4E	2013 E	2014 E	2015 E	2016 E
Product sales	**$24,327**	**$6,313**	**$5,062**	**$8,830**	**$6,091**	**$26,296**	**$31,918**	**$29,878**	**$35,683**
% of total revenue	*95.0%*	*94.5%*	*93.9%*	*96.1%*	*94.0%*	*94.8%*	*96.2%*	*94.2%*	*95.4%*
YOY Growth	*39.6%*	*-0.8%*	*-12.9%*	*86.1%*	*-17.8%*	*8.1%*	*21.4%*	*-6.4%*	*19.4%*
License & royalty income	**$0**	**$0**	**$0**	**$12**	**$16**	**$28**	**$75**	**$402**	**$403**
% of total revenue	*0.0%*	*0.0%*	*0.0%*	*0.1%*	*0.2%*	*0.1%*	*0.2%*	*1.3%*	*1.1%*
R&D contracts, grants, milestones	**$1,283**	**$365**	**$332**	**$350**	**$375**	**$1,422**	**$1,200**	**$1,425**	**$1,300**
% of total revenue	*5.0%*	*5.5%*	*6.2%*	*3.8%*	*5.8%*	*5.1%*	*3.6%*	*4.5%*	*3.5%*
Total Revenues	$25,610.5	$6,678.2	$5,393.5	$9,192.0	$6,482.0	$27,745.9	$33,193.1	$31,705.1	$37,385.9
YOY Growth	*32.1%*	*0.4%*	*-11.3%*	*83.6%*	*-17.6%*	*8.3%*	*19.6%*	*-4.5%*	*17.9%*
Cost of Revenues	$14,820	$3,984	$3,112	$5,616	$3,825	$16,538	$18,832	$16,732	$19,447
Gross Income	$10,790	$2,694	$2,281	$3,576	$2,657	$11,208	$14,361	$14,973	$17,939
Gross Margin	*42.1%*	*40.3%*	*42.3%*	*38.9%*	*41.0%*	*40.4%*	*43.3%*	*47.2%*	*48.0%*
Product Margin	*39.1%*	*36.9%*	*37.5%*	*36.4%*	*37.2%*	*37.1%*	*41.0%*	*44.0%*	*45.5%*
Research & Development	$4,487	$1,045	$1,501	$1,095	$1,102	$4,743	$4,721	$4,620	$4,855
% R&D	*17.5%*	*15.7%*	*27.8%*	*11.9%*	*17.0%*	*17.1%*	*14.2%*	*14.6%*	*13.0%*
Selling General & Admin	$4,852	$1,162	$1,160	$1,774	$1,089	$5,185	$6,340	$6,309	$7,253
% SG&A	*18.9%*	*17.4%*	*18.9%*	*19.3%*	*16.8%*	*18.7%*	*19.1%*	*19.9%*	*19.4%*
Operating Income	$1,452	$487	($380)	$707	$466	$1,280	$3,301	$4,044	$5,831
Operating Margin	*5.7%*	*7.3%*	*-7.0%*	*7.7%*	*7.2%*	*4.6%*	*9.9%*	*12.8%*	*15.6%*
Other income (expense)	$1	$0	$8	$0	$0	$8	$0	$0	$0
Interest income, net	($2)	$1	$1	$3	$0	$5	$50	$95	$125
Pre-Tax Income	$1,451	$488	($371)	$710	$466	$1,292	$3,351	$4,139	$5,956
Taxes	$509	$170	($130)	$282	$185	$507	$1,330	$1,643	$2,364
Tax Rate	*35.1%*	*35.0%*	*39.7%*	*39.7%*	*39.7%*	*39.2%*	*39.7%*	*39.7%*	*39.7%*
Net Income	$942	$317	($241)	$428	$281	$785	$2,020	$2,496	$3,591
YOY Growth	*-84.8%*	*-26.9%*	*-178.1%*	*-246.5%*	*-42.8%*	*-16.6%*	*157.3%*	*23.5%*	*43.9%*
Net Margin	*3.7%*	*4.7%*	*-4.5%*	*4.7%*	*4.3%*	*2.8%*	*6.1%*	*7.9%*	*9.6%*
GAAP EPS	$0.11	$0.04	($0.03)	$0.04	$0.02	$0.08	$0.17	$0.21	$0.31
Adjusted EPS	$0.17	$0.05	($0.04)	$0.06	$0.04	$0.12	$0.28	$0.34	$0.40
YOY Growth	*-84.9%*	*-33.4%*	*-167.1%*	*-200.6%*	*-52.3%*	*-28.2%*	*128.0%*	*23.5%*	*43.9%*
Weighted Avg. Shares O/S	8,419	8,699	9,260	11,625	11,625	10,302	11,625	11,625	11,625

Brian Marckx, CFA

HISTORICAL ZACKS RECOMMENDATIONS



DISCLOSURES

The following disclosures relate to relationships between Zacks Investment Research ("ZIR"), Zacks & Company (ZCO") and Zacks Small-Cap Research ("Zacks SCR") and the issuers covered by the Zacks SCR analysts in the Small-Cap Universe.

ZIR or Zacks SCR Analysts do not hold or trade securities in the issuers which they cover. Each analyst has full discretion on the rating and price target based on their own due diligence. Analysts are paid in part based on the overall profitability of Zacks SCR. Such profitability is derived from a variety of sources and includes payments received from issuers of securities covered by Zacks SCR for non-investment banking services. No part of analyst compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in any report or blog.

ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Zacks SCR has never received compensation for investment banking services on the small-cap universe. Zacks SCR does not expect received compensation for investment banking services on the small-cap universe. Zacks SCR has received compensation for non-investment banking services on the small-cap universe, and expects to receive additional compensation for non-investment banking services on the small-cap universe, paid by issuers of securities covered by Zacks SCR. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, investment research, and investment management.

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but is not guaranteed as to accuracy and does not purport to be complete. Because of individual objectives, the report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed by Zacks SCR Analysts are subject to change. Reports are not to be construed as an offer or the solicitation of an offer to buy or sell the securities herein mentioned.

ZCO and Zacks SCR are separate legal entities. ZCO is U.S. broker-dealer registered with the U.S. Securities and Exchange Commission and a member of the Financial Industry Regulatory Authority and the Securities Investor Protection Corp. This report is for your information only and is not an offer to sell, or a solicitation of an offer to buy, the securities or instruments through ZCO.

Zacks SCR uses the following rating system for the securities it covers. Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters. Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters. Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution of Zacks Ratings is as follows on the 1025 companies covered: Buy/Outperform- 15.2%, Hold/Neutral- 77.8%, Sell/Underperform – 6.1%. Data is as of midnight on the business day immediately prior to this publication.

© Copyright 2013, Zacks Investment Research. All Rights Reserved.