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Zacks Small-Cap Research

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Chembio Diagnostics Inc. (CEMI- NASDAQ)

CEMI: Some Weakness In US POC HIV, DPP Holding Up Nice, Pipeline Progress Continues

OUTLOOK

Buy

N/A

\$4.74

\$7.00

06/14/2010

CLIA Waiver granted for DPP HIV assay. CEMI signed distribution agreements and also bldg direct sales force to sell direct in the U.S. Int'l lateral flow sales remain variable which negatively impacted 2014 revenue. DPP international sales have been very strong with FIOCRUZ still very active and HIV/Syph launch in Mexico the drivers in 2014. DPP HIV/Syph in Brazil could be major catalyst. Next up could be the U.S. mrkt. – clinical trials for which slated to commence 2H 2015.

Pipeline progress continues - recent partnerships announced to develop Ebola, Dengue Fever, Febrile illness, TBI, malaria and cancer test on DPP platform. CEMI also focused on complementary revenue opportunities including add'I R&D contracts/grants, expansion of international commercialization footprint, and potentially in-licensing products.

We are maintaining our Buy rating.

SUMMARY DATA

Target Price

Current Recommendation

Prior Recommendation

Current Price (08/10/15)

Date of Last Change

52-Week High 52-Week Low One-Year Return (%) Beta Average Daily Volume (sh)	\$5.25 \$3.34 40.18 0.56 18,141	Risk Level Type of Stock Industry			Sma			Average, all-Blend Products
Shares Outstanding (mil) Market Capitalization (\$mil) Short Interest Ratio (days) Institutional Ownership (%) Insider Ownership (%)	10 \$46 1.27 19 6	Rever (millions	•) Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	(D	ec)
Annual Cash Dividend Dividend Yield (%)	\$0.00 0.00	2014 2015 2016 2017	\$5.81 A \$6.23 A		·	\$7.10 A \$6.82 E	\$26. \$29.	65 A 50 E 47 E 78 E
5-Yr. Historical Growth Rates Sales (%) Earnings Per Share (%) Dividend (%)	14.8 -40.6 N/A		sted Earni Q1 (Mar)	Q2 (Jun)	Q3) (Sej	p) (D	24 ec)	Year (Dec)
P/E using TTM EPS P/E using 2015 Estimate P/E using 2016 Estimate	N/A N/A 22.3	2014 2015 2016 2017	-\$0.04 A -\$0.09 A	•			.07 A .06 E	-\$0.16 A -\$0.34 E -\$0.09 E \$0.17 E
Zacks Rank	N/A	Zacks	Projected	EPS Grov	vth Rate -	Next 4 Ye	ars %	NA

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WHAT'S NEW

Q2 2015: Softness in U.S. HIV, DPP Holding Up Well, Pipeline Moving Closer to Commercial Products..

Chembio reported financial results for the second quarter ending June 30th. The top and bottom lines missed our numbers by about 3% and \$325k, respectively. Revenue shrank more than we were expecting as a result in softening of the overall HIV POC testing market and lower than modeled international lateral flow sales (which are near impossible to model given reliance on tenders), which was partially offset by better than anticipated DPP sales. This was true even despite DPP sales falling in Mexico, an area that has been a recent boon for CEMI with their DPP HIV-Syphilis test. This miss to net loss was a combination of lower revenue and higher R&D, the latter mostly attributed to R&D contracts. But while revenue and expenses weren't a particular highlight, product margin, at 41.5%, was the widest since Q2 2012, benefitting in part from manufacturing efficiency initiatives implemented in 2H 2014.

The softness in U.S. lateral flow sales, which were down \$219k (18%) qoq and 30% yoy (yoy is not particularly relevant given a \$1.1M payment in Q2 2014 from termination of Alere/STAT-PAK dist agreement), may reflect, at least to some degree, systemic weakness of the overall U.S. HIV POC market as some testing shifts to 4th-gen laboratory testing. OSUR noted as much on their Q2 call explaining this contributed to the 15% yoy drop in U.S. sales of their HIV POC business. But relative to CEMI's U.S. HIV sales, some of it may also be from CEMI's sales force still climbing the productivity curve. While we had been modeling roughly mid-single digit growth coming from CEMI's total HIV franchise (i.e. lateral flow and DPP) in the U.S., we have since updated this to more flattish qoq growth.

Relative to DPP - sales continue to mostly come from Brazil which was a major driver of the top-line in 2014 and helped push 1H 2015 DPP sales up by just better than \$100k. We continue to expect DPP Brazil sales to remain significant throughout the remainder of 2015. We also think DPP HIV/Syphilis, which while slipping in Mexico in Q2, has been very successful in that country since the launch in late-2013, to be a big winner in Brazil as well. The test was approved by Brazilian regulators in February of this year.

So while we continue to see headwinds during the current year and now model a 4% topline contraction (revised lower from a 2% decrease) compared to 2014, we continue to see several near-term catalysts that can turn revenue back to positive growth. Despite some US POC HIV testing moving to the lab, we believe the recently launched DPP HIV assay can be a formidable and significant revenue generator for CEMI – on the Q2 call management characterized the progress of introduction as "slow and steady." DPP HIV/Syph - we think this is a needle-mover in Brazil and has the potential to very big in the U.S. as well – it is expected to enter clinical trials in the U.S. in 2H 2015 – this is the pipeline candidate that CEMI is most focused on. So with the pipeline getting deeper and deeper, we think there could be a fairly steady stream of new products reaching the market and if that happens, these could provide additional tailwinds to revenue for some time to come.

CEMI also announced that they are breaking down their business activities into three areas; sexually transmitted diseases, fever and tropical diseases, and licensing and partnerships. The fever and tropical diseases has been a relatively new area for CEMI but they appear fully dedicated to exploiting this. Malaria and Ebola as well as Dengue Fever are initial priorities. The company also hopes to have a fever multiplex panel developed – which would presumably cover these three as well as up to four other fevers. Management noted that progress continues on these various programs, although chose not to provide specific development timelines.

On the partnership side they continue to work on development of an assay for CTE and sports concussions as well as a cancer diagnostic and flu-immune status test.

Q2 Financials

Q2 revenue of \$6.7 million was down 10%, up 8% sequentially and about 3% lower than our \$7.0 million estimate. Revenue in the year-earlier period includes about \$1.1 million related to the termination of the Alere/STAT-PAK distribution agreement. The increase from Q1 2015 came from a \$1.5 million jump in DPP sales – not much in the way of disclosure about the big increase, although DPP sales have been all over the place so this could be timing in Brazil. As noted CEMI mentioned some relative weakness in DPP Mexico sales in Q2 although they hope for this to show regained strength.

Probably, and unfortunately, more fundamental might be the 18% drop in U.S. lateral flow sales – some of which most likely relates to the move from POC to the lab (next-gen test) for HIV. But we think DPP HIV has potential to

stem the tide, at least to some degree, given the potential accuracy advantages over OSUR's saliva/blood OraQuick (POC) HIV assay. CEMI's test was CE Marked in June and the company expects to launch in Europe in Q4 this year. While a potential contributor, we don't model much from the EU given relatively lower rates of HIV and more reliance on lab testing.

Over the near term we have Brazil related sales continuing to contribute the major portion of DPP revenue. This includes the DPP HIV/Syph test which was launched in February in Brazil.

Modeling international lateral flow has been and will likely continue to be a cat-herding exercise as no one seems to have much in the way of insight into when aid tenders might come. Our Q2 number, \$1.6 million turned out to be way too high with this coming in at \$1.2 million. By comparison this was \$1.6 million in Q1. Our model assumes about \$2.1 million total in 2H – this is probably the line-item that has the most potential to beat on the upside.

Gross and product margins at 45.0% and 41.5%, respectively, were the widest since Q1 2012 and bolstered by a combination of benefits from recent manufacturing cost initiatives as well as a healthy amount of contract revenue in the quarter. We continue to expect to see improvement in both product and gross margin in 2015 as compared to 2014.

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 ~35.1% is ~90% non-cash until they exhaust (which, based on our current model will occur sometime in 2019 or 2020) their entire deferred tax asset which stood at \$4.5 million at the end of Q2.

Q2 adjusted net income and EPS of approximately (\$874)k and (\$0.09) compares to our (\$549)k and (\$0.06) estimates. Most of the difference relates to a combination of the miss on revenue and higher than modeled R&D expense.

Cash

Excluding changes in working capital, cash used in operations was \$491k in Q2. CEMI exited Q2 with \$1.6M in cash and equivalents, compared to \$2.8M at the end of Q1. CEMI currently has an A/R balance of about \$8.9 million – about \$7.4 million of which relates to one customer. Management noted on the call that they believe this is collectible and expects to bring the balance down. Cash from A/R collections and a \$2 million bank line (if needed) should provide sufficient near-term liquidity.

Business / Pipeline Update:

HIV U.S. Direct Roll-Out

Highlights since the close of 2013 include CEMI terminating the domestic distribution agreement with Alere related to their STAT-PAK HIV rapid lateral flow test. The agreement terminated on June 3, 2014. Alere will continue to distribute CEMI's other lateral flow HIV test, branded as Clearview Complete. CEMI has already hired a small sales force including a director of sales, director of marketing and a handful of sales reps to handle direct sales of STAT-PAK as well as the DPP products.

Management has indicated their initial direct sales strategy for STAT-PAK HIV is focused on public health facilities. With CLIA waiver of DPP HIV now granted they expect to incrementally grow their direct sales force which will be complemented with third-party distribution - the company now has at least three distribution agreements in place which includes the major medical device companies, McKesson/PSS, Fisher Healthcare and Henry Schein.

Malaria, Ebola, Febrile illness...

CEMI is collaborating with Gaithersburg, MD-based Integrated Biotherapeutics in development of DPP tests for Ebola and Febrile illness for the POC market. Integrated Bio is providing Ebola antibodies that CEMI noted have already undergone initial testing, in development of an Ebola assay.

Since the October collaboration announcement, CEMI has made substantive progress which includes successful lab testing of the Ebola assay, signing a research agreement with CDC to develop and validate both an Ebola and Febrile illness test, testing the Ebola assay at CDC's lab, submitting pre-qualification for DPP Ebola to WHO as well as to FDA for Emergency Use Authorization. Most recently, CEMI sold ~10k Ebola assays to CDC which are

expected to be field tested in W. Africa this quarter (Q3). Following field testing next would hopefully be WHO prequalification and initial OUS commercialization. We think a DPP Ebola test, depending on continued successful development, could possibly be a fairly near-term contributor.

Relative to febrile illness, CEMI should be able to leverage much of what they have learned from the U.S. government grant that was awarded to the company in May 2013 for development of a POC assay for five infectious diseases associated with febrile illness. CEMI envisions a commercial product under their recent collaboration that would be a multiplex test on the DPP platform that could test for several infectious diseases including Malaria, Ebola, Febrile illness, Dengue fever and several others.

On the Q2 call management talked about this further, noting they hope to be able to develop a multiplex fever panel which could include up to seven fevers. They are working on securing outside funding for the project. They are focused on an Ebola/Malaria combo test – which follows CDC's advisory in June urging testing of not just Ebola but other infectious diseases such as malaria. CEMI hopes to have an Ebola/Malaria combo test to CDC in Q3 for testing. Specific to the malaria marker, they are working with the Gates Foundation to develop an ultrasensitive (greater than 10-fold improvement in sensitivity of world's leading POC lateral flow malaria assay) POC malaria assay.

And specific to Dengue fever, the company entered into another recent collaboration - this time with an unnamed partner, for development of a DPP POC test for Dengue fever. CEMI hopes to begin field testing the Dengue assay in Q3.

Traumatic Brain Injury...

Another recent addition to the product pipeline was announced in January when CEMI disclosed they are collaborating with the Concussion Science Group (CSG) Division of Perseus Science Group LLC in development of a DPP test for traumatic brain injury. Under the agreement CSG will make milestone payments to CEMI in 2015.

Traumatic brain injuries have received significant mainstream media attention of late due to their association with injuries of NFL players and a potential cause for severe depression and some resultant suicides. Identifying the presence of traumatic brain injuries is currently often not possible until either well into their progression or, in some cases, until an autopsy is done. A reliable POC test that could identify traumatic brain injuries therefore would likely have massive appeal.

Cancer...

Recently signed a collaboration agreement with an unnamed (international diagnostics) company for development of a DPP cancer test. The type of cancer was not disclosed

Influenza...

CEMI has had an ongoing DPP Influenza development program which most recently included a follow-on grant awarded in November 2014 which is in collaboration with a private company which is working on behalf of the U.S. CDC. The product is a multiplex, seven band flu test which completed optimization with CDC and Battelle. CEMI hopes to continue development upon additional CDC funding.

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 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. The company has not provided a recent update on their HCV program.

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

We think this DPP Syphilis / HIV combo test is a potentially significant needle-mover for CEMI - initial meaningful revenue contribution from which materialized during 2014. In late October 2013 CEMI announced the test launched in Mexico and that they received their first P.O. for the test from their Mexican distributor. That same month they also announced that the test was accepted on the USAID list of products eligible to be used in international procurement programs. This is the only Syphilis / HIV combo test currently on the USAID waiver list. Management noted the test contributed several million \$ worth of revenue during the first 12 months following launch in Mexico. The test looks like it could have potentially significant appeal in emerging markets, particularly for prenatal testing where relatively high rates of both HIV and syphilis are commonplace and programs to reduce the incidence of mother-to-child transmission have been implemented.

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). Most recently CEMI announced that FDA indicated to the company that performance of the test will need to comply with a new (higher) standard. CEMI has been under discussions with FDA relative to design of a study which would eventually be used to support regulatory filing in the U.S. On the Q2 2015 call management noted that they are working on clinical trial site selection and hope to commence the study later in 2015.

Could Be A Big Contributor in 2015 With Launch in Brazil...

The success of the DPP HIV/Syphilis test in Mexico may be duplicated, or even surpassed in Brazil where it was granted approval by regulators in February 2015. We think the test makes a substantial contribution to product revenue - potentially starting during the current year. CEMI has also submitted the test for evaluation by CDC and for pre-qualification by WHO for its global procurement programs.

DPP HIV Multiplex P24 Antigen / Antibody

CEMI continues to look to leverage the multiplexing 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 multiplex 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 was initially only sold ex-U.S. In late October 2013 Alere received FDA approval of their test (Determine HIV 1/2 Ag/Ab Combo) and in December the test was granted CLIA waiver, allowing it to be used at the point-of-care. While it's currently difficult to judge the potential demand for a P24 test, in part due to somewhat conflicting performance results in clinical studies (earlier P24 test versions suffered from poor sensitivity, although Alere's published clinical test results for their Determine test indicate relatively very high sensitivity and specificity) the advantages of an accurate rapid test that can detect both acute and chronic HIV infection would likely have broad appeal.

In August 2013 CEM announced that they expected to pursue a similar test using its DPP technology. CEMI most recently noted (on the Q1 2015 call) that development progress continues on this test including completing a prototype and securing a source for antibodies.

Complementary Revenue Opportunities

CEMI has recently dedicated a greater focus on what we characterize as complementary revenue opportunities essentially non-core commercialization activities that have the potential to provide incremental revenue with little additional operating expense. The company has had significant success over the years with scoring R&D contracts and grants from private and government entities related to development of various diagnostic tests which have provided a meaningful contribution to both revenue and margins. Management has indicated that they will be very active in pursuing future contracts.

The other complementary revenue opportunities come from expanding their international footprint with their existing suite of products, something that management has clearly put additional effort into recently and is expected to be an ongoing focus going forward. In May 2013 CEMI entered into an assembly and distribution agreement with Labtest Diagnostica of Brazil whereby CEMI will sell Labtest components to certain DPP tests which will be assembled and sold by the Brazilian company. CEMI will receive a royalty on sales.

In February 2014 CEMI penned technology transfer agreement with RVR Diagnostics or Malaysia whereby RVR will manufacture and distribute the DPP HIV 1/2 and DPP HIV/Syphilis tests in parts of Asia (ex-China) and will pay CEMI a royalty on sales as well as consummation and milestone fees. Chembio indicated that they think this RVR opportunity, in particular, could have significant revenue potential.

OUR OUTLOOK

Revenue

We look for 2015 revenue of \$26.5 million, implying a decrease of 4% from 2014. We think there may continue to be some lingering near-term softness in domestic lateral flow sales as CEMI completes the transition from distribution via Alere. Some shifting of HIV testing from POC to the new-gen lab tests could bring in the overall market, although we think DPP HIV has room to grow in the U.S. International lateral flow sales, as indicated, are particularly difficult to predict given their inherent variability – we model about 92% growth in 2015, which is more of a function of 2014 being a relatively weak year – this line, we think, has the most potential to beat our number on the upside as we show no sequential growth from 1H to 2H 2015.

DPP sales were extraordinarily strong in 2014 as FIOCRUZ continued to purchase well beyond their minimum purchase requirements for most of the products under the tech transfer agreement and uptake of DPP HIV/Syphilis in Mexico was tremendous. Given no obvious indication that FIOCRUZ will trigger the tech transfer and an expectation that DPP HIV/Syphilis comes out strong in Brazil, we think single-digit contraction of the DPP portfolio is a reasonable estimate for 2015. And while DPP in Mexico was somewhat soft in Q2, we see no reason why this cannot turn back to growth in the second half of the year.

We think commercialization of the pipeline should begin to make a more substantive contribution going into 2016.

We currently do not model any of the pipeline products – launch of any of which could provide some upside to our estimates.

Net Income / EPS

We look for adjusted net income and EPS of (\$3.3)M and (\$0.34) in 2015, compared to (\$1.1) million and (\$0.16) in 2014.

RECOMMENDATION / VALUATION

We continue to use OSUR as a comp for valuation purposes. OSUR trades at approximately 2.6x 2015 estimated sales and 2.1x EV/2015 sales. P/S comp values CEMI at ~\$7.50/share, EV/S values CEMI at ~\$6/share. We use the approximate average, \$7/share, as our price target. We are maintaining our Buy recommendation.

FINANCIAL STATEMENTS

INCOME STATEMENT

Chembio Diagnostics, Inc.

	2014 A	Q1A	Q2A	Q3E	Q4E	2015 E	2016 E	2017 E	2018 E
Product sales	\$25,950	\$5,615	\$6,322	\$6,149	\$6,063	\$24,148	\$27,471	\$33,513	\$36,233
% of total revenue	93.9%	90.1%	94.1%	91.2%	88.9%	91.1%	93.2%	93.7%	93.7%
YOY Growth	-5.7%	14.5%	-12.8%	-15.2%	-7.4%	-6.9%	13.8%	22.0%	8.1%
License & royalty income	\$24	\$7	\$8	\$139	\$316	\$470	\$697	\$899	\$1,037
% of total revenue	0.1%	0.1%	0.1%	2.1%	4.6%	1.8%	2.4%	2.5%	2.7%
R&D contracts, grants,	\$1,672	\$609	\$387	\$452	\$438	\$1,886	\$1,300	\$1,365	\$1,400
milestones % of total revenue	51,072 6.0%	9.8%	5 .8%	543 6.7%	5430 6.4%	7.1%	4.4%	3.8%	\$1,400 3.6%
Total Revenues	\$27,645.3	\$6,231.1	\$6,716.2	\$6,740.0	\$6.817.0	\$26,504.3	\$29.467.5	\$35,776.4	\$38,669.
YOY Growth	\$27,043.3 -6.4%	7.2%	-9.5%	-7.9%	-3.9%	-4.1%	\$29,407.3 11.2%	\$55,770.4 21.4%	\$36,009. 8.1%
Cost of Revenues	-0.4% \$16,831	\$3,545	\$3,697	\$3,782	-3.9% \$3,668	\$14,691	\$15,878	\$19,035	\$20,435
Gross Income	\$10,814	\$2,687	\$3,019	\$2,958	\$3,149	\$11,813	\$13,589	\$16,741	\$18,234
Gross Margin	39.1%	43.1%	45.0%	43.9%	46.2%	44.6%	46.1%	46.8%	47.2%
Product Margin	35.1%	36.9%	41.5%	38.5%	39.5%	40.8%	42.2%	43.2%	43.6%
Research & Development	\$4,833	\$1,585	\$1,757	\$1,812	\$1,841	\$6,995	\$6,244	\$5,352	\$4,719
% R&D	17.5%	25.4%	26.2%	26.9%	27.0%	26.4%	21.2%	15.0%	12.2%
Selling General & Admin	\$7,532	\$1,978	\$2,160	\$2,116	\$1,950	\$8,204	\$8,280	\$9,624	\$10,209
% SG&A	27.2%	31.7%	32.2%	31.4%	28.6%	31.0%	28.1%	26.9%	26.4%
Operating Income	(\$1,550)	(\$875)	(\$898)	(\$970)	(\$642)	(\$3,385)	(\$935)	\$1,765	\$3,307
Operating Margin	-5.6%	-14.1%	-13.4%	-14.4%	-9.4%	-12.8%	-3.2%	4.9%	8.6%
Other income (expense)	(\$6)	\$0	\$0	\$0	\$0	\$0	\$0	\$0	\$0
Interest income, net	\$6	\$1	\$0	\$1	\$1	\$3	\$18	\$66	\$81
Pre-Tax Income	(\$1,550)	(\$874)	(\$898)	(\$969)	(\$641)	(\$3,382)	(\$917)	\$1,831	\$3,388
Taxes	(\$413)	(\$228)	(\$234)	(\$339)	(\$224)	(\$1,024)	(\$344)	\$687	\$1,270
Tax Rate	26.6%	26.0%	26.0%	35.0%	35.0%	37.5%	37.5%	37.5%	37.5%
Net Income	(\$1,137)	(\$647)	(\$664)	(\$630)	(\$417)	(\$2,357)	(\$573)	\$1,145	\$2,117
YOY Growth	-314.1%	187.8%	354.9%	132.7%	-16.0%	107.3%	-75.7%	-299.7%	85.0%
Net Margin	-4.1%	-10.4%	-9.9%	-9.3%	-6.1%	-8.9%	-1.9%	3.2%	5.5%
GAAP EPS	(\$0.12)	(\$0.07)	(\$0.07)	(\$0.06)	(\$0.04)	(\$0.24)	(\$0.06)	\$0.11	\$0.20
Adjusted EPS	(\$0.16)	(\$0.09)	(\$0.09)	(\$0.10)	(\$0.06)	(\$0.34)	(\$0.09)	\$0.17	\$0.30
YOY Growth	-302.1%	136.4%	286.9%	252.3%	-7.1%	103.8%	-76.3%	-287.2%	81.9%
Weighted Avg. Shares O/S	9,529	9,625	9,628	9,728	9,788	9,692	9,955	10,620	10,800
					Brian Marckx, CFA				

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The current distribution is as follows: Buy/Outperform- 29.2%, Hold/Neutral- 51.4%, Sell/Underperform – 16.3%. Data is as of midnight on the business day immediately prior to this publication.