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Chembio Diagnostics Inc. (CEMI- NASDAQ)

CEMI: Strong Lateral Flow Picking Up Slack From FIOCRUZ Decline

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/14/2010
Current Price (11/11/13)	$3.56
Target Price	**$10.00**

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 2012. 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	**$3.30**
One-Year Return (%)	**-12.62**
Beta	**0.28**
Average Daily Volume (sh)	**39,417**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$33**
Short Interest Ratio (days)	**1.87**
Institutional Ownership (%)	**19**
Insider Ownership (%)	**15**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**22.6**
Earnings Per Share (%)	**-28.2**
Dividend (%)	**N/A**
P/E using TTM EPS	**20.9**
P/E using 2013 Estimate	**19.8**
P/E using 2014 Estimate	**14.2**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Value**
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	$9.62 A	$6.69 E	$28.38 E
2014					$31.89 E
2015					$31.04 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	$0.11 A	$0.05 E	$0.18 E
2014					$0.25 E
2015					$0.33 E

Zacks Projected EPS Growth Rate - Next 4 Years % **25**

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WHAT'S NEW

Q3 2013

Q3 2013 revenue of $9.6 million was up 92% yoy and buoyed in part by the $5.3 million order from an international procurement agency for one of the lateral flow products that Chembio had previously announced. CEMI recognized $3.9 million of this order in Q3 (the remainder almost evenly split between Q2 and Q4) which helped push international lateral flow sales up almost 390% yoy to $4.9 million, just slightly below our $5.0 million estimate. Meanwhile, U.S. lateral flow sales remained very strong as well, posting 83% yoy growth to $2.2 million and better than our $2.0 million estimate. DPP sales to FIOCRUZ at $1.9 million also came in incrementally better than our estimate, at $1.7 million. Importantly, management noted that their prior guidance for full-year FIOCRUZ related revenue of approximately $6 million still holds, which implies they should record $2+ million in FIOCRUZ DPP sales in Q4.

Total revenue beat our estimate of $9.2 million by about 5% and consisted of $9.0 million in product sales (vs. $8.8 million estimate) and $572k in R&D contracts and grants (vs. $350k estimate). We look for revenue of $6.7 million in Q4, the anticipated sequential decrease due to the bulk of the large international order being booked in Q3. Our 2013 full year estimate now stands at $28.4 million, implying yoy growth of about 11%. Noteworthy is that we think CEMI will post double-digit revenue growth in 2013 despite an anticipated decline in FIOCRUZ related sales of $4 million or more (40%+).

Gross margin at 42.2% was also better than our estimate, of 38.9%. Q3 operating expenses were $3.0 million, in-line with our $2.9 million estimate. With CLIA waiver studies for the DPP HIV test now nearly completed, we expect to see a decrease in R&D expense in Q4.

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 2015) their entire deferred tax asset which stood at $3.9 million at the end of Q3. Q3 adjusted net income and EPS of approximately $1.0 million and $0.11 were ahead our $682k and $0.06 estimates. We now look for adjusted EPS of $0.18 for the full year 2013.

Cash
Excluding changes in working capital, cash from operations was an inflow of $1.27 million. CEMI exited Q3 with $8.1 million in cash and equivalents and no debt. CEMI also has a $2.0 million credit line (untapped at Q3 quarter-end).

Business / Pipeline Update

Highlights over the last few quarters include discussions with Alere about that company potentially extending the agreement to remain CEMI's distribution partner for the company's lateral flow products. CEMI noted that Alere has stated that they want to continue this arrangement. A decision is expected in the near-term. As a reminder, earlier this year Alere announced that they expect to launch a competing product (HIV 1/2 antibody / p24 antigen rapid test) which, per terms of the distribution agreement, allows CEMI to make the agreement non-exclusive or (for one of the lateral flow tests) terminate the agreement altogether. If CEMI does decide to sell these tests with their own sales force, which they will assemble in 2014 for their DPP products for the U.S. market, they will realize a significantly higher average sales price given that Alere currently clips a sizeable margin.

The other most noteworthy recent highlights are that timelines for CLIA waiver of the DPP HIV test are tracking earlier expectations and CEMI launched their HIV-Syphilis test in Mexico, which was also accepted on the USAID list of products eligible to be used in international procurement programs. Relative to the DPP HIV test for the U.S. market, CEMI is still shooting to have the CLIA waiver application submitted in Q4 (mid-November) and hopes to have the CLIA waiver in Q1 2014 with launch anticipated shortly afterwards.

DPP HIV, U.S.
FDA approval for all sample types (oral fluid, whole blood, serum, and plasma) came in December 2012. Studies to support CLIA waiver started in April and are now wrapping up. CEMI expects to submit the CLIA waiver application in mid-November and hopes to have the CLIA waiver in Q1 2014 with launch anticipated 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 2013 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

In late October CEMI announced the test launched in Mexico and that they received their first P.O. for the test from their Mexican distributor. In October they also announced that the test was accepted on the USAID list of products eligible to be used in international procurement programs. This will be the only Syphilis / HIV combo test currently on the USAID waiver list. The test could potentially have 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) - 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 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 of this year Alere received FDA approval of test (Determine HIV 1/2 Ag/Ab Combo) and is currently undergoing CLIA waiver studies. Alere noted that they expect to submit a CLIA waiver application in Q4, meaning the test is potentially widely distributed beginning next year. 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 CEM announced that they expected to pursue a similar test using its DPP technology. CEMI most recently noted that they will continue to evaluate their strategy for this test.

OUR OUTLOOK

Revenue

We now look for 2013 revenue of $28.4 million, increased from $27.8 million prior to Q3 results, most of the change as a result of the beat in Q3. Our $28.4 million estimate implies growth of about 11%. Noteworthy is that we think CEMI will post double-digit revenue growth in 2013 despite an anticipated decline in FIOCRUZ related sales of $4 million or more (40%+).

Net Income / EPS

We now model adjusted net income and EPS of $1.7 million and $0.18 in 2013 (compared to $1.4 million and $0.17 in 2012), increased from $1.2 million and $0.12 prior to Q3 results.

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 $10.00/share. We are maintaining our Outperform rating.

INCOME STATEMENT

Chembio Diagnostics, Inc.

	2012 A	Q1A	Q2A	Q3A	Q4E	2013 E	2014 E	2015 E	2016 E
Product sales	**$24,327**	**$6,313**	**$5,062**	**$9,045**	**$6,062**	**$26,482**	**$30,854**	**$29,214**	**$34,806**
% of total revenue	*95.0%*	*94.5%*	*93.9%*	*94.0%*	*90.7%*	*93.3%*	*96.7%*	*94.1%*	*95.3%*
YOY Growth	*39.6%*	*-0.8%*	*-12.9%*	*90.6%*	*-18.2%*	*8.9%*	*16.5%*	*-5.3%*	*19.1%*
License & royalty income	**$0**	**$0**	**$0**	**$1**	**$5**	**$6**	**$75**	**$402**	**$403**
% of total revenue	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.1%*	*0.0%*	*0.2%*	*1.3%*	*1.1%*
R&D contracts, grants, milestones	**$1,283**	**$365**	**$332**	**$572**	**$619**	**$1,888**	**$962**	**$1,425**	**$1,300**
% of total revenue	*5.0%*	*5.5%*	*6.2%*	*5.9%*	*9.3%*	*6.7%*	*3.0%*	*4.6%*	*3.6%*
Total Revenues	$25,610.5	$6,678.2	$5,393.5	$9,617.6	$6,686.0	$28,375.5	$31,891.2	$31,040.4	$36,509.2
YOY Growth	*32.1%*	*0.4%*	*-11.3%*	*92.1%*	*-15.0%*	*10.8%*	*12.4%*	*-2.7%*	*17.6%*
Cost of Revenues	$14,820	$3,984	$3,112	$5,561	$3,758	$16,417	$18,512	$16,652	$19,666
Gross Income	$10,790	$2,694	$2,281	$4,056	$2,928	$11,959	$13,379	$14,389	$16,844
Gross Margin	*42.1%*	*40.3%*	*42.3%*	*42.2%*	*43.8%*	*42.1%*	*42.0%*	*46.4%*	*46.1%*
Product Margin	*39.1%*	*36.9%*	*38.5%*	*38.5%*	*38.0%*	*38.0%*	*40.0%*	*43.0%*	*43.5%*
Research & Development	$4,487	$1,045	$1,501	$1,602	$1,280	$5,428	$4,910	$4,800	$4,925
% R&D	*17.5%*	*15.7%*	*27.8%*	*16.7%*	*19.1%*	*19.1%*	*15.4%*	*15.5%*	*13.5%*
Selling General & Admin	$4,852	$1,162	$1,160	$1,380	$1,123	$4,825	$5,900	$6,146	$7,192
% SG&A	*18.9%*	*17.4%*	*21.5%*	*14.3%*	*16.8%*	*17.0%*	*18.5%*	*19.8%*	*19.7%*
Operating Income	$1,452	$487	($380)	$1,074	$524	$1,705	$2,569	$3,443	$4,726
Operating Margin	*5.7%*	*7.3%*	*-7.0%*	*11.2%*	*7.8%*	*6.0%*	*8.1%*	*11.1%*	*12.9%*
Other income (expense)	$1	$0	$8	$0	$0	$8	$0	$0	$0
Interest income, net	($2)	$1	$1	$1	$0	$3	$50	$95	$125
Pre-Tax Income	$1,451	$488	($371)	$1,076	$524	$1,716	$2,619	$3,538	$4,851
Taxes	$509	$170	($130)	$359	$184	$582	$1,040	$1,404	$1,926
Tax Rate	*35.1%*	*35.0%*	*35.1%*	*33.4%*	*35.0%*	*33.9%*	*39.7%*	*39.7%*	*39.7%*
Net Income	$942	$317	($241)	$717	$341	$1,134	$1,579	$2,133	$2,925
YOY Growth	*-84.8%*	*-26.9%*	*-178.1%*	*-345.1%*	*-30.7%*	*20.4%*	*39.3%*	*35.1%*	*37.1%*
Net Margin	*3.7%*	*4.7%*	*-4.5%*	*7.5%*	*5.1%*	*4.0%*	*5.0%*	*6.9%*	*8.0%*
GAAP EPS	$0.11	$0.04	($0.03)	$0.07	$0.03	$0.12	$0.16	$0.21	$0.27
Adjustments	$471	$153	($117)	$323	$165	$524	$936	$1,264	$1,509
Adjusted Net Income	$1,413	$471	($358)	$1,040	$506	$1,658	$2,515	$3,397	$4,435
Adjusted EPS	$0.17	$0.05	($0.04)	$0.11	$0.05	$0.18	$0.25	$0.33	$0.42
YOY Growth	*-84.9%*	*-33.4%*	*-167.1%*	*-281.6%*	*-36.3%*	*5.0%*	*30.4%*	*32.5%*	*32.0%*
Weighted Avg. Shares O/S	8,419	8,699	9,260	9,824	9,850	9,408	10,050	10,250	10,650

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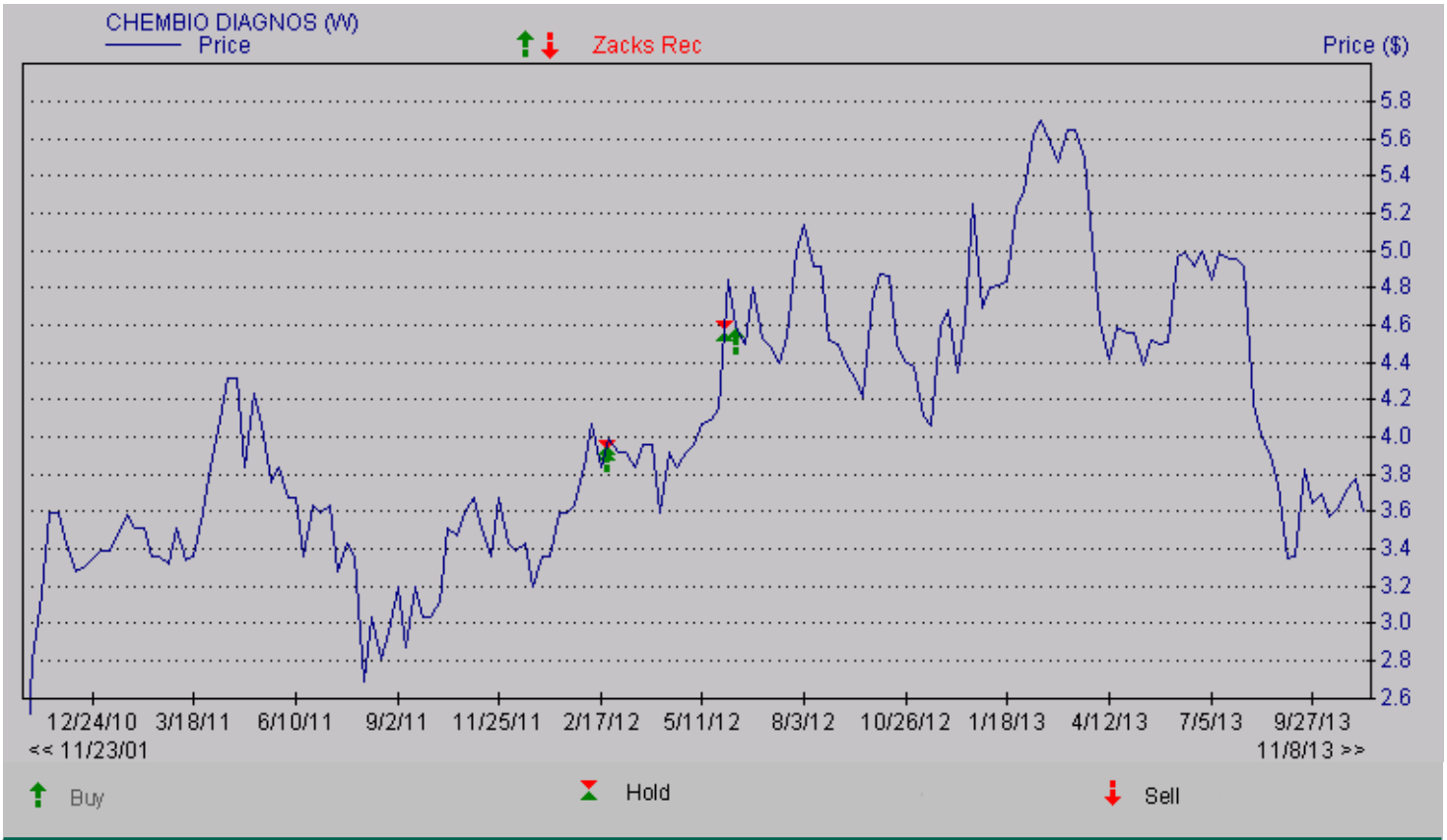
HISTORICAL ZACKS RECOMMENDATIONS



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