Zacks Small-Cap Research

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Biomerica Inc (BMRA-OTCBB)

BMRA: Q2 Results Inline. IBS Product May Follow De Novo FDA Pathway

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	01/23/2013
Current Price (10/19/15)	$0.85
Target Price	**$2.20**

OUTLOOK

Revenue growth had recently softened but is bouncing back. We think this recent strength will continue, despite a huge recent hiccup in Asia sales – this should now be ironed out. New distribution in Europe and product launches have facilitated stabilizing revenue there. Meanwhile, U.S. sales have been softer and may continue to be so. Could see a big-winner with new GI test (still under dvlmpnt). We continue to see very little to no downside risk in the share price at this level. We see only upside as revenue is now returning to positive growth.

SUMMARY DATA

52-Week High	**$1.44**
52-Week Low	**$0.70**
One-Year Return (%)	**0.00**
Beta	**0.47**
Average Daily Volume (sh)	**2,236**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$7**
Short Interest Ratio (days)	**1.23**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**26**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-1.3**
Earnings Per Share (%)	**42.0**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2016 Estimate	**N/A**
P/E using 2017 Estimate	**28.3**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Value**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Aug)	Q2 (Nov)	Q3 (Feb)	Q4 (May)	Year (May)
2015	1.03 A	1.13 A	1.30 A	1.50 A	4.96 A
2016	1.29 A	1.44 E	1.63 E	1.74 E	6.10 E
2017					7.10 E
2018					7.70 E

Earnings per Share

	Q1 (Aug)	Q2 (Nov)	Q3 (Feb)	Q4 (May)	Year (May)
2015	-$0.03 A	-$0.03 A	-$0.02 A	-$0.03 A	-$0.04 A
2016	-$0.01 A	-$0.02 E	-$0.00 E	$0.00 E	-$0.03 E
2017					$0.03 E
2018					$0.07 E

Zacks Projected EPS Growth Rate - Next 5 Years % **NA**

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WHAT'S NEW……

Q1 Results: Inline With Our Estimates, IBS Product May Follow De Novo FDA Pathway…

Biomerica reported financial results for their fiscal first quarter ending August 2015. Results were very much inline with our estimates including total revenue as well as sales to both Europe and Asia, all of which were just about dead-on with our numbers. Meanwhile a slight beat on both gross margin and OpEx resulted in moderately better than estimated net loss. We have made no meaningful net changes to our model following Q1 results and continue to look for revenue to grow sequentially throughout the year, largely driven by a resurgence of growth in Asia.

While Asia sales fell from $522k in Q4 to $433k in Q1, we had anticipated this and sales were still ahead of every other quarter in fiscal 2015. As noted in our previous update, Asia sales in Q4 2015 may have benefitted from product sold in Q3 but not shipped until the following period – which we think reflects the sequential decrease from Q4 to Q1. And, as a reminder, BMRA noted in the 10-K that their Asian distributor "informed management that it anticipates improved sales results in (fiscal) 2016."

As we have noted in the past, while taking longer than initially anticipated, Asia sales have recently begun rebounding and we continue to see no reason why they will not eventually return to historical levels. Asia accounted for 43% of total revenue in fiscal 2013 when sales from that area were $2.8M, which compares to $1.0M, or just 21% of total revenue in 2015. But of this $1.0M in 2015, 88% was generated in the second half – which is indicative of the recent recovery. We currently model Asia sales of just better than $2M in 2016 and have them nearing historical peak levels in 2017.

Meanwhile U.S. sales have remained relatively tepid as a result of lower sales of the company's EZ Detect colon cancer test for screening programs. While indications were that a certain chain store delayed its screening program from Q3 to Q4 2015, we think that based on the relatively poor showing of U.S. sales in Q4 (down 15% yoy and 17% sequentially), that perhaps this customer did not purchase at the level that had been anticipated. Following Q4 results we downwardly adjusted our U.S. sales for 2016. This downward revision, however, may not have been significant enough as U.S. sales again underperformed our estimate in Q1 ($187k A vs. $240k E). As such, we have again trimmed our estimates for the U.S. market.

Relative to Europe, sales have been much more consistent than compared to either the U.S. or Asia. Sales in Europe were $619k in Q1, down 18% yoy and down 10% from Q4 but a hair better than our $609k estimate. We note that sales in the prior year comparable quarter ($752k) were a difficult comp as this was the highest level of sales in Europe since Q4 2013 and the second highest since Q4 2010. BMRA also notes in their earnings release that Q1 sales in Europe may have been impacted by order timing.

And as a reminder, the company's European distributor recently merged with another company which, due to the integration process, had negatively impacted sales of Biomerica's products in that region. The relatively stronger showing in Q4 2015 and Q1 2016 may indicate that any lingering integration issues may now be less of a headwind - although we note that we continue to take somewhat of a cautious approach and model low single digit contraction for Europe sales in 2016. Europe has become a particularly important territory for BMRA, especially when Asia sales were tumbling, and accounted for more than 50% of the company's total revenue in 2015 and 48% in Q1 2016. Our numbers for 2016 could prove conservative and offer the potential for upside if sales in Europe begin to strengthen.

And BMRA may soon see significantly more sales coming from South America, which has historically generated very little in revenue for the company. South America sales were just $19k and $22k in fiscal 2014 and 2015, respectively, accounting for less than 1% of revenue in both periods. But with recent Brazilian regulatory approval of several of the company's products and a new distribution partner signed, South American sales could become more relevant. This may already be bearing some fruit, with S. America generating $17k of revenue in Q1, better than our $15k estimate.

On the operational front, BMRA is moving further towards the possibility of bringing their irritable bowel syndrome (IBS) test to market. In January the company filed the first set of patents related to the product and followed with bringing on a scientific advisory board to help further guide their strategy related to the pipeline candidate. The board includes Dr. Doug Drossman, an expert in IBS who has authored several articles and publications on the disorder. The company held a conference call in early July, details of which we discuss below. Most recently the

company announced that they have had initial discussions with FDA regarding the regulatory pathway and requisite supporting clinical studies. BMRA indicated in late September that they expect (assuming FDA acceptance) to pursue the de novo pathway. The de novo pathway allows manufacturers of novel low-risk (Class I and II) products for which there is no predicate to avoid the much costlier and time-consuming PMA route. BMRA will need to apply to FDA requesting the de novo route – the application will include information about the product, such as its intended use, evidence of safety and effectiveness, benefits, etc. FDA has 120 days to make a determination. We expect to hear more about the plan for clinical studies and the regulatory pathway in the near future.

Financials
Q1 revenue of $1.3 million was up 24% yoy, down 14% sequentially and inline with our $1.3 million estimate. Total revenue as well as sales in Asia and Europe all came in just about dead-on with our respective estimates. However, U.S. sales were about 22% ($53k) weaker than our number – which was mostly offset by better than anticipated sales in S. America ($5k beat) and the Middle East ($24k beat).

OpEx were $498k, about 13% lower than our $571k estimate and down slightly from $527k in Q4. This is lowest level of operating expenses since fiscal Q1 2014 (August 2013). And at just 39% of revenue, total OpEx were the relatively (relative to sales) second lowest since fiscal Q3 2014. OpEx could increase considerably if and when BMRA pursues further development of the IBS test – we currently do not model either expenses or revenue related to the test as it is still in the feasibility stage – although we will update our model accordingly if and when appropriate. BMRA noted in the "subsequent events" section of the 10-K that their board of directors approved an agreement with an investment banker to raise up to $3M via the sale of restricted common stock – while not stated in the filing, this could potentially relate to initial funding of clinical studies in support of the IBS test development. We expect we'll hear more about the company's plans in this regard in the near future.

Meanwhile, gross margin showed a moderate rebound from Q4 (31.2%), coming in at a more healthy 32.7% in Q1, which was also ahead of our 31.6% estimate. But, GM jumps around quite a bit from q-to-q (as an example, it was 35% in Q3 2015). We model GM to widen with growth in revenue – which has the effect of diluting fixed costs. We also think GM will benefit if and when U.S. sales begin to turn around.

Q1 net loss and EPS were $72k and ($0.01), compared to our $158k loss and ($0.02) estimates.

Cash
The balance sheet remains solid. BMRA exited Q1 2016 with $893k in cash, down slightly from $1.1M at the end of fiscal 2015. Excluding changes in working capital, BMRA used $33k for operating activities in Q1. The balance sheet remains debt free. Book value at the end of Q1 stood at $5.5 million or approximately $0.73/share. We continue to believe that book value should put a floor on valuation of the company.

IBS Test Conference Call

Biomerica recently held a conference call regarding its under-development irritable bowel syndrome (IBS) diagnostic. As a reminder, in January the company filed the first set of patents related to the product and, more recently, brought on a scientific advisory board to help further guide their strategy related to the pipeline candidate. The board includes Dr. Doug Drossman, an expert in IBS who has authored several articles and publications on the disorder. Dr. Drossman is also the President of the Rome Foundation, a non-profit organization on the leading edge of GI disorder research and developer of the Rome III Questionnaire, which is a widely used clinical diagnostic for IBS. The advisory board, which also includes three other key opinion leaders in the GI and IBS field, will help guide BMRA through the FDA approval process.

BMRA has been largely tight-lipped about details of the IBS product as they lock down IP (several patents have been filed). And while management still didn't provide specifics (on such things as biomarkers) on this recent conference call (patents are still pending), they did confirm our prior suspicions that it is a diagnostic for food allergens (i.e. diet) which may be responsible for onset or aggravation of IBS. Additional details include;

- will identify certain trigger foods that may cause or exacerbate IBS symptoms
- will help physicians in guiding treatment protocol including putting the patient on a specific dietary regimen. This is different then other IBS tests which only focus on diagnosing presence of the disease. BMRA's test would be the first to both help diagnose IBS and to help guide treatment decisions
- test will be available for use in both the clinical lab and physician office settings

- would be reimbursed under existing CPT codes. As reimbursement is critical for maximizing early adoption, availability of payment under existing CPT codes is a significant benefit
- test is patent-pending at USPTO. BMRA has also filed for seven additional patents covering the technology

Zack Irani also did a nice job of framing the market opportunity for the test. Highlights of which included;

- Diagnostic cost of IBS in the U.S. is approximately $10.5B in annual direct costs and over $30B when including indirect costs
- IBS afflicts as much as 20% of the U.S. population, 25% of Japan, and 22%+ each of China and the U.K
- IBS is a top 10 reason for primary care doctor visits
- IBS is difficult to diagnose and difficult to treat
- Current diagnosis is more of ruling out other conditions than it is of a specific diagnosis for IBS
- A new blood-based test, recently highlighted on CBS nightly news in a segment titled *New tests offer hope for millions of patients with IBS*, has a false-negative rate of 56%. We think this highlights how elusive it has been to develop a reliable and effective IBS diagnostic. In addition, these new tests only aim to diagnose the disease but do not guide treatment decisions like BMRA's test is expected to do

As we noted in prior updates, we think having Dr. Drossman on board is a significant vote of confidence in the potential of BMRA's IBS product, which we continue to think could eventually be a big winner for the company. Once the initial patent is granted and published, we'll know more specifics about the test. We also expect management will be providing updates – including more about the plan for clinical studies and the regulatory pathway.

Maintaining Outlook / Recommendation

We continue to think sales to Asia will continue to rebound over the near term and will eventually return to legacy levels. The new product launches in China should be an additional facilitator to growth of sales in that country. Growth in Asian sales is what is driving almost all of our modeled top-line growth in 2016. And while we continue to look for European sales to be a significant contributor to total revenue, we are hesitant to model much more in the way of growth from current levels – this could prove to be a conservative outlook and will be updated if appropriate. Meanwhile U.S. sales have been disappointing, falling 17% in 2015 – which likely relates, at least in part, to softer sales of EZ Detect. As noted, we have twice trimmed our sales outlook for the U.S. Some of the weakness in the U.S. may be offset by increasing, and potentially much more substantial, sales in South America as well as the Middle East – both of which outperformed our numbers in Q1.

We look for 2016 revenue and EPS of $6.1 million (+23%) and ($0.03) and for this to grow to $8.5 million and $0.09 in fiscal 2019. We are maintaining our Buy rating. Our price target is $2.15/share.

As we noted in our recent prior updates, over the mid-to-longer terms we think Biomerica will be looking to further exploit their existing technology. We view management's priorities as such that they will be focused on accelerating growth through bringing higher potential and novel products to market which we think likely fits into this growth strategy. We note that our current model does not incorporate an assumed contribution from "home run" type products - although we think given the company's expertise in certain disease areas (including GI, foodborne, women's health, and infectious disease), along with patentable and perhaps underexploited technology platforms and management's renewed focus on accelerating growth over the long-term, that big-winner type products could very well materialize over the coming years. The IBS product, still under development and for which U.S. patent applications were just recently filed, could potentially be a big-winner product – we will be eagerly awaiting further development updates on this product.

VALUATION / RECOMMENDATION

We use a comparable cohort of five companies of various market capitalizations in the medical diagnostics space with products/services that target the POC and/or clinical lab markets to value BMRA. Based on several metrics and excluding the negative values, BMRA is valued between $1.14 and $2.71 per share. Average is approximately $2.20/share.

The balance sheet remains solid. BMRA exited fiscal 2015 with $900k in cash and equivalents and no debt. Book value at the end of fiscal Q1 2016 stood at $5.5 million or approximately $0.73/share. We continue to believe that book value should put a floor on valuation of the company.

We recommend buying the shares up to our $2.20/share target price and are maintaining our Buy rating.

Comparable Multiples

Ticker	P/E (ttm)	P/E (FY1)	P/E (FY4)	P/Book	EV / EBITDA (ttm)	P/S (ttm)	P/S (FY1)
TRIB	19.6	20.4	10.9	1.3	14.6	2.7	2.7
CEMI	N/A	N/A	11.0	2.6	N/A	1.7	1.7
VIVO	21.2	20.0	11.7	4.6	11.8	3.9	3.8
ERB	N/A	N/A	N/A	5.1	NA	3.9	4.0
ABAX	35.0	30.0	17.1	4.5	20.0	4.8	4.5
Average	**25.3**	**23.5**	**12.7**	**3.6**	**15.5**	**3.4**	**3.4**

FY1, FY4 = forecast year 1, forecast year 4

Value Based On Comp:

	P/E (ttm)	P/E (FY1)	P/E (FY4)	P/Book	P/S (ttm)	P/S (FY1)	AVG
BMRA	-$0.74	-$0.69	$1.14	$2.63	$2.31	$2.71	**$2.20**

FINANCIAL MODEL

Biomerica Inc.

	2015 A	Q1A	Q2E	Q3E	Q4E	2016 E	2017 E	2018 E	2019 E
Total Revenues	$4,962.4	$1,287.0	$1,444.2	$1,624.7	$1,739.3	$6,095.1	$7,068.9	$7,665.1	$8,497.2
YOY Growth	*-3.1%*	*24.4%*	*27.4%*	*25.0%*	*16.3%*	*22.8%*	*16.0%*	*8.4%*	*10.9%*
Cost of Goods Sold	$3,420.6	$865.6	$979.1	$1,043.1	$1,141.0	$4,028.7	$4,517.0	$4,691.1	$5,174.8
Gross Income	$1,541.8	$421.4	$465.0	$581.6	$598.3	$2,066.4	$2,551.9	$2,974.1	$3,322.4
Gross Margin	*31.1%*	*32.7%*	*32.2%*	*35.8%*	*34.4%*	*36.1%*	*36.1%*	*38.8%*	*39.1%*
SG&A	$1,478.8	$339.7	$414.5	$438.7	$436.6	$1,629.4	$1,710.7	$1,770.6	$1,843.9
% SG&A	*29.8%*	*26.4%*	*28.7%*	*27.0%*	*25.1%*	*27.1%*	*24.2%*	*23.1%*	*21.7%*
R&D	$733.6	$158.0	$176.0	$183.0	$165.0	$682.0	$631.0	$588.0	$622.0
% R&D	*14.8%*	*12.3%*	*12.2%*	*11.3%*	*9.5%*	*11.2%*	*8.9%*	*7.7%*	*7.3%*
Operating Income	($670.6)	($76.2)	($125.5)	($40.0)	($3.2)	($245.0)	$210.2	$615.4	$856.5
Operating Margin	*-13.5%*	*-5.9%*	*-8.7%*	*-2.5%*	*-0.2%*	*-4.0%*	*3.0%*	*8.0%*	*10.1%*
Total Other Income (Expense)	$24.1	$3.9	$4.5	$4.5	$4.5	$17.4	$14.2	$18.0	$24.0
Pre-Tax Income	($646.5)	($72.3)	($121.0)	($35.5)	$1.3	($227.6)	$224.4	$633.4	$880.5
Tax expense (benefit)	($315.0)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$95.0	$132.1
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*15.0%*	*15.0%*
Net Income	($331.5)	($72.3)	($121.0)	($35.5)	$1.3	($227.6)	$224.4	$538.4	$748.4
YOY Growth	*53.6%*	*-61.7%*	*-87.5%*	*37.8%*	*78.0%*	*-31.3%*	*-198.6%*	*139.9%*	*39.0%*
Net Margin	*-6.7%*	*-5.6%*	*-8.4%*	*-2.2%*	*0.1%*	*-3.7%*	*3.2%*	*7.0%*	*8.8%*
EPS	($0.04)	($0.01)	($0.02)	($0.00)	$0.00	($0.03)	$0.03	$0.07	$0.09
YOY Growth	*49.9%*	*-61.9%*	*-87.9%*	*38.2%*	*78.0%*	*-32.6%*	*-192.9%*	*138.5%*	*37.5%*
Diluted Shares O/S	7,552	7,582	7,585	7,760	7,825	7,688	8,160	8,210	8,300

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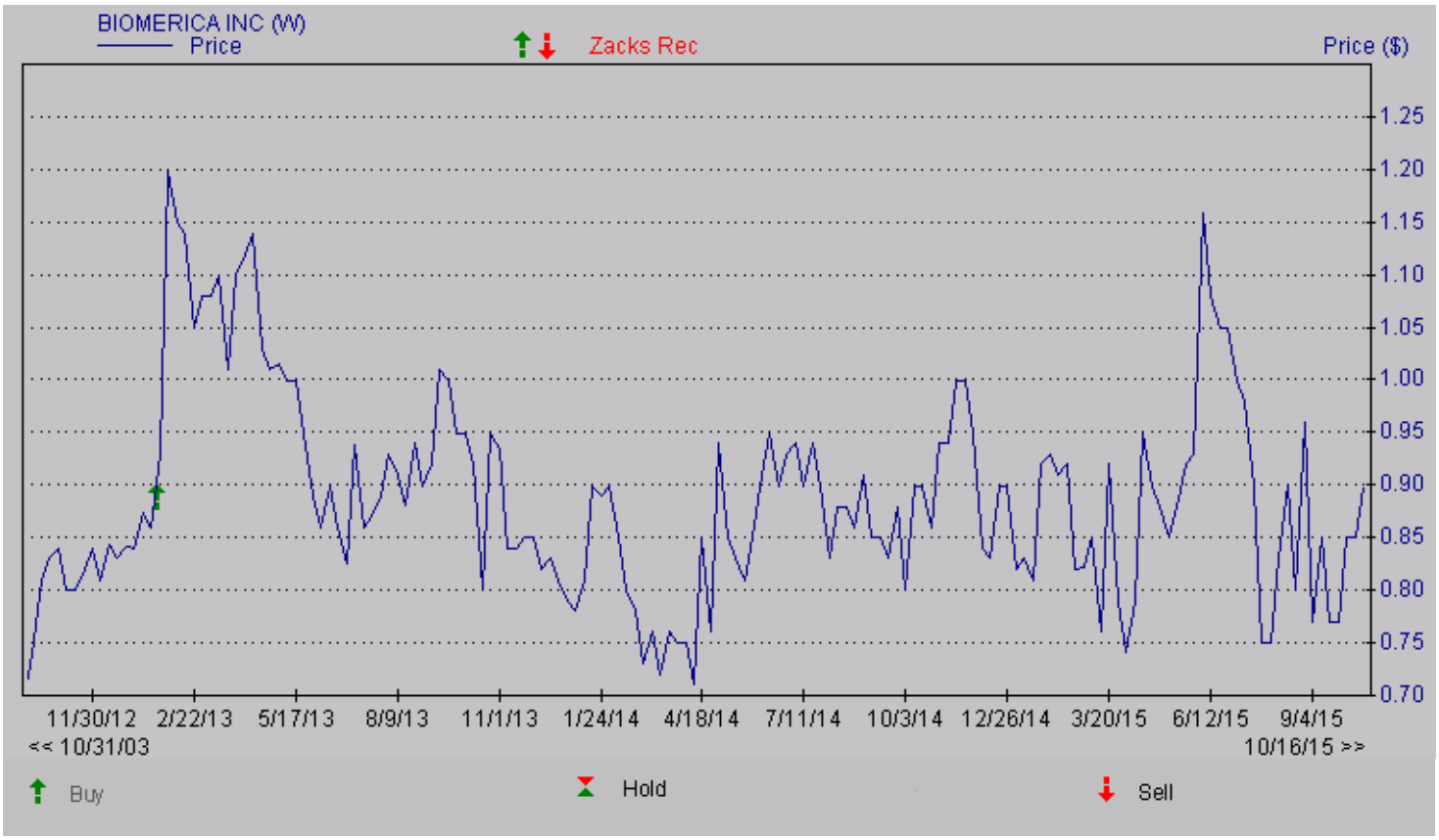
HISTORICAL ZACKS RECOMMENDATIONS



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Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

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