Zacks Small-Cap Research

January 19, 2016

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Biomerica Inc (BMRA-OTCBB)

BMRA: Q2 Results: Europe Softens. IBS Advisory Board Beefed Up Further

OUTLOOK

Revenue growth had recently softened but is bouncing back. Asia sales returning to growth, although some weakness in the U.S. and Europe. New distribution in Europe and product launches could firm up 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 development). Recently beefed up IBS Advisory Board, could be a harbinger for further development progress. We continue to see very little to no downside risk in the share price at this level. Balance sheet remains solid.

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	01/23/2013
Current Price (01/19/16)	$1.25
Target Price	**$2.25**

SUMMARY DATA

52-Week High	**$1.50**
52-Week Low	**$0.70**
One-Year Return (%)	**0.00**
Beta	**-0.95**
Average Daily Volume (sh)	**5,189**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$10**
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	**N/A**
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	1.17 A	1.49 E	1.67 E	5.60 E
2017					6.51 E
2018					7.06 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	-$0.01 A	-$0.01 E	$0.00 E	-$0.03 E
2017					-$0.00 E
2018					$0.03 E

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

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WHAT'S NEW……

Q2 Results: Softer European Sales, BMRA Points to Order Timing, Expects Rebound in Q3…

Biomerica reported financial results for their fiscal second quarter ending November 2015. Results, in both revenue and operating expenses, underperformed our estimates, although this was partially offset by relatively strong gross margin. The majority of the $279k miss on revenue relates to much more tepid sales in Europe than what we had expected. Management notes in the 10-Q that this is related to order timing and weaker sales in the period but indicated that they expect a rebound in the following quarter and hope to expand distribution to other countries in Europe. Meanwhile, revenue from the other itemized territories, including the U.S. and Asia, came in largely inline with our numbers. And while total revenue fell from Q1 (i.e. sequentially), importantly it posted positive growth on a yoy basis (albeit barely).

Through the first six months of fiscal 2016, revenue is up 13% from the same period in 2015. Almost all of this growth is from Asia and benefitting from the recent switch in distributors in that territory. But while Asia has rebounded nicely from the prior year, U.S. and Europe have not. U.S. sales, while mostly in agreement with our estimate ($218k A vs $233 E), have been relatively weak since fiscal Q3 2015, which was around the time that BMRA noted that a certain chain store delayed its screening program using EZ Detect. U.S. sales are down about 14% through the first six months of fiscal 2016.

Europe has been particularly weak compared to the prior year, down 32% in Q2 and 24% through the first half of the year. European sales came in $192k lighter ($473k A vs $665k E) than our estimate. BMRA has noted for the last two quarters that order timing may have been an issue. 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. While we had hoped to see this issue, and any order timing, be resolved by now, we have made some downward revisions to our Europe sales estimates as we think there may be some ongoing softness. We had previously modeled a low single-digit contraction in Europe sales through fiscal 2016 – we now model low double-digit contraction. As Europe still accounts for just over 40% of total sales, the recent weakness in this territory has had a meaningful impact on revenue. If distribution does expand to other European countries, that could have a positive effect on revenue.

A brighter spot has been S. America, which has historically generated very little in revenue for the company. South America sales were just $19k and $22k in all of 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 sales of $49k in 1H 2016.

On the operational front, BMRA is moving further towards the possibility of bringing their irritable bowel syndrome (IBS) test to market. In early calendar 2015 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 July 2015, details of which we discuss below. Then later in 2015 the company announced that they 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.

The most recent compelling news as it relates to a potential IBS product came in early January 2016 when BMRA announced that Charles Carter, PharmD, was appointed as a senior advisor. Clearly the appointment of Dr. Carter was made to help guide BMRA on development of their IBS product. Carter was Salix Pharmaceuticals' Director of Medical Affairs and instrumental in getting that company's IBS-D (irritable bowel syndrome with diarrhea) candidate, Xifaxan, through FDA regulatory approval. Salix's product portfolio, which is mostly focused on gastrointestinal disorders, spans 10+ GI drugs, screening preps and other treatments. Xifaxan, which is also approved for over hepatic encephalopathy, was their largest selling product when the company was acquired by Valeant

Pharmaceuticals (NYSE: VRX) in April 2015. Valeant ponied up over $11B to acquire Salix, which represented an almost 44% equity premium. Valeant cited the strong market for GI products as an impetus for the acquisition.

So while there are still few details on exactly what BMRA's IBS product entails, we view the appointments of Drs. Drossman and Carter as additional early validation of what the potential of the product may hold. And clearly a growing interest in GI products, as evidenced by Valeant's acquisition of Salix, is a promising sign for potential market demand.

Financials
Q2 revenue of $1.4 million was up 3% yoy, down 9% sequentially and 19% lower than our $1.2 million estimate. Asia and U.S. sales were mostly in-line with our estimates while Europe came in considerably lower.

OpEx were $622k, about 5% higher than our $591k estimate and up from $498k in Q1. The difference from Q1 and our estimate relates to higher R&D expense – which likely relates to development and patent filings for the IBS product. OpEx could increase considerably if and when BMRA pursues further development of the IBS test – we currently only model incidental expenses (i.e. – no clinical trial expenses have yet to be modeled) related to the test as it is still in the feasibility stage – although we will update our model accordingly if and when appropriate. BMRA recently disclosed 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 came in relatively strong at 35.4% - this compares to 32.7% in Q1 and 31.1% for the full year 2015. But, GM jumps around quite a bit from q-to-q. 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.

Q2 net loss and EPS were $67k and ($0.01), compared to our $121k loss and ($0.02) estimates. Net loss benefitted from $129k income tax benefit in the quarter as a result of a FASB accounting update.

Cash
The balance sheet remains solid. BMRA exited Q2 2016 with $643k in cash but subsequent to quarter-end collected A/R which brought the cash balance up to approximately $1.1 million. Excluding changes in working capital, BMRA used $133k for operating activities in Q2. The balance sheet remains debt free. Book value at the end of Q2 stood at $5.5 million or approximately $0.72/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 2015 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. In early January 2016 BMRA announced that Charles Carter, PharmD, was appointed as a senior advisor. Carter was Salix Pharmaceuticals' Director of Medical Affairs and instrumental in getting that company's IBS-D candidate, Xifaxan, through FDA regulatory approval.

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 (and now Dr. Carter) 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. 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 and another 14% in 1H 2016 – 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 the first six months of 2016.

We look for 2016 revenue and EPS of $5.6 million (+13%) and ($0.03) and for this to grow to $7.8 million and $0.06 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, high and low values, BMRA is valued at approximately $2.25/share.

The balance sheet remains solid with no debt. Current cash balance is approximately $1.1 million. Book value at the end of fiscal Q2 2016 stood at $5.5 million or approximately $0.72/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 $2.25/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	12.4	24.0	7.9	1.2	14.3	2.5	2.5
CEMI	N/A	N/A	11.0	2.3	N/A	1.6	1.5
VIVO	22.0	20.0	11.8	4.7	11.7	4.1	4.0
ERB	N/A	N/A	N/A	3.8	972.0	2.7	2.8
ABAX	36.0	33.0	21.3	4.9	22.0	5.3	5.1
Average	**23.5**	**25.7**	**13.0**	**3.4**	**16.0**	**3.2**	**3.2**

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	-$0.69	-$0.78	$0.83	$2.47	$2.19	$2.35	**$2.27**

FINANCIAL MODEL

Biomerica Inc.

	2015 A	Q1A	Q2A	Q3E	Q4E	2016 E	2017 E	2018 E	2019 E
Total Revenues	$4,962.4	$1,287.0	$1,165.0	$1,485.1	$1,665.0	$5,602.1	$6,505.0	$7,059.0	$7,826.9
YOY Growth	*-3.1%*	*24.4%*	*2.8%*	*14.3%*	*11.4%*	*12.9%*	*16.1%*	*8.5%*	*10.9%*
Cost of Goods Sold	$3,420.6	$865.6	$753.0	$953.4	$1,092.2	$3,664.3	$4,156.7	$4,320.1	$4,766.6
Gross Income	$1,541.8	$421.4	$412.0	$531.7	$572.8	$1,937.8	$2,348.3	$2,738.9	$3,060.3
Gross Margin	*31.1%*	*32.7%*	*35.4%*	*35.8%*	*34.4%*	*34.6%*	*36.1%*	*38.8%*	*39.1%*
SG&A	$1,478.8	$339.7	$391.6	$415.8	$441.2	$1,588.3	$1,697.8	$1,764.7	$1,815.8
% SG&A	*29.8%*	*26.4%*	*33.6%*	*28.0%*	*26.5%*	*27.1%*	*26.1%*	*25.0%*	*23.2%*
R&D	$733.6	$158.0	$230.2	$183.0	$165.0	$736.2	$704.0	$661.0	$647.0
% R&D	*14.8%*	*12.3%*	*19.8%*	*12.3%*	*9.9%*	*13.1%*	*10.8%*	*9.4%*	*8.3%*
Operating Income	($670.6)	($76.2)	($209.9)	($67.2)	($33.5)	($386.7)	($53.5)	$313.1	$597.5
Operating Margin	*-13.5%*	*-5.9%*	*-18.0%*	*-4.5%*	*-2.0%*	*-6.9%*	*-0.8%*	*4.4%*	*7.6%*
Total Other Income (Expense)	$24.1	$3.9	$14.0	$4.5	$4.5	$26.9	$14.2	$18.0	$24.0
Pre-Tax Income	($646.5)	($72.3)	($195.8)	($62.7)	($29.0)	($359.8)	($39.3)	$331.1	$621.5
Tax expense (benefit)	($315.0)	$0.0	($129.0)	$0.0	$0.0	($129.0)	$0.0	$49.7	$93.2
Tax Rate	*0.0%*	*0.0%*	*65.9%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*15.0%*	*15.0%*
Net Income	($331.5)	($72.3)	($66.8)	($62.7)	($29.0)	($230.8)	($39.3)	$281.5	$528.3
YOY Growth	*53.6%*	*-61.7%*	*-127.9%*	*27.4%*	*87.1%*	*-30.4%*	*-83.0%*	*-816.2%*	*87.7%*
Net Margin	*-6.7%*	*-5.6%*	*-5.7%*	*-4.2%*	*-1.7%*	*-4.1%*	*-0.6%*	*4.0%*	*6.7%*
EPS	($0.04)	($0.01)	($0.01)	($0.01)	($0.00)	($0.03)	($0.00)	$0.03	$0.06
YOY Growth	*49.9%*	*-61.9%*	*-128.2%*	*27.5%*	*86.9%*	*-31.0%*	*-84.1%*	*-811.8%*	*85.6%*
Diluted Shares O/S	7,552	7,582	7,587	7,600	7,700	7,617	8,160	8,210	8,300

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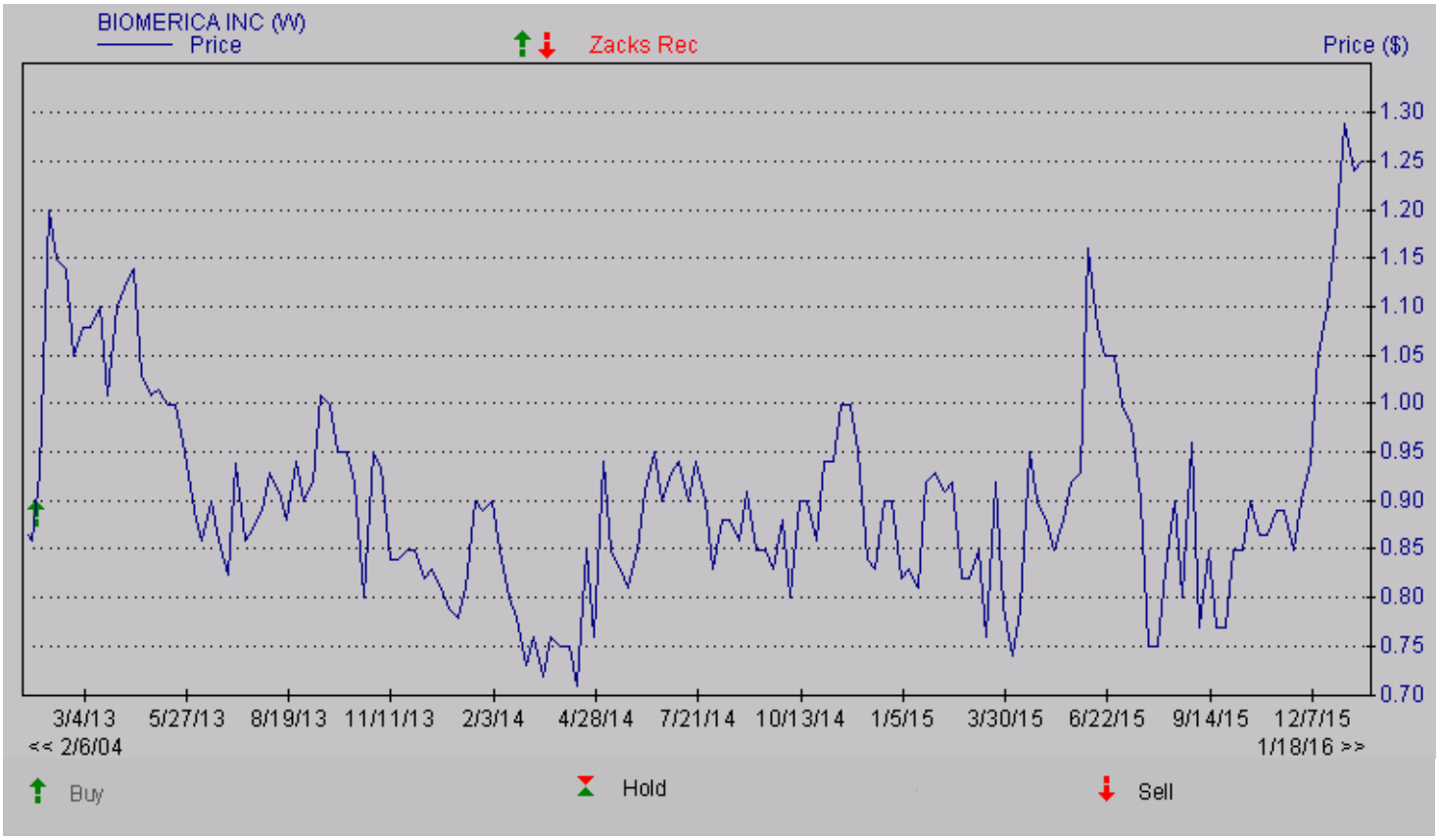

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Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

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