Zacks Small-Cap Research

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Biomerica Inc (BMRA-OTCBB)

BMRA: Q3 Results: Revenue Continues to Show Growth. Operational Progress on inFoods IBS Test

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	01/23/2013
Current Price (04/15/16)	$1.54
Target Price	**$2.25**

OUTLOOK

Revenue growth had recently softened but is bouncing back. Asia and U.S sales firming back up, although weakness continues in Europe. Look for possibility pf new distribution and product launches to help sales there. Could see a big-winner with inFoods, the under-development IBS test. Progress includes onboarding highly experienced scientific advisory board and validation of intellectual property protection. FDA has indicated regulatory pathway could be relatively simple de novo. We expect to hear more details in near future on next steps. Board recently began buying shares in open market as sign of confidence in inFoods' potential. Balance sheet remains solid.

SUMMARY DATA

52-Week High	**$1.71**
52-Week Low	**$0.70**
One-Year Return (%)	**0.00**
Beta	**-1.04**
Average Daily Volume (sh)	**1,414**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$12**
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 (%)	**N/A**
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	1.36 A	1.32 E	5.14 E
2017					5.94 E
2018					6.44 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	-$0.02 A	-$0.01 E	-$0.05 E
2017					-$0.03 E
2018					$0.01 E

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

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WHAT'S NEW……

Q3 Results: Revenue Slightly Lower Than Our Estimate But Continues to Show Growth….

Biomerica reported financial results for their fiscal third quarter ending February 2016. Revenue came in moderately less than what we were looking for, gross margin was very narrow relative to recent history as well as our estimate and operating expenses were just about on the nose with our number. The net result was operating loss coming in at $269k, well below our $63k (loss) estimate.

But despite the revenue miss to our estimate ($1.49M vs $1.36M), the top-line has trended higher every quarter this fiscal year as compared to last. Q3 revenue was up 5% from the same period in fiscal 2015 and through the first nine months of the year, revenue has grown 10%. And despite the relatively weak gross margin in Q3, profitability is also up (albeit slightly) from the prior year – net loss improved from $610k to $555k in the first three quarters of each respective year.

And BMRA has made meaningful operational progress during fiscal 2016 – most notably with their IBS test product candidate ('inFoods') including further development activities, assemblage of an expert scientific advisory board to help guide strategy and with intellectual property protection. So while fiscal 2016 has not exactly been a blow-out year relative to the financials, it is slightly improved in that regard relative to the previous year and, importantly, BMRA continues to move down the road with what could potentially and eventually be their most significant product to-date.

On a year-over-year basis Europe continues to experience sliding sales – falling 8% in Q3 and 20% through the first nine months. But that territory was by far the best performing in 2015, making the comps particularly challenging. On a positive note as it relates to Europe, sales increased by 15% from Q2 (i.e. sequentially). But we continue to model a double digit slide in European revenue for the full year. The reason for the continued weakness is not completely clear, although BMRA had previously noted that order timing may have been a contributor – which could be related to integration issues from the recent merger of the company's European distributor with another company. Falling revenue in Europe has had a disproportionate impact on total company revenue given that revenue from the region accounted for 55% of the entire top-line in 2015, which has fallen to 43% YTD. Had European revenue just remained flat from 2015, total revenue growth would have been 21% instead of the actual 10% through the first nine months. So if Europe rebounds, that could have a significant positive impact on the company's financials. Management had previously mentioned that they hope to expand distribution to other countries in Europe, which could be one possible catalyst to making that happen.

Meanwhile, U.S. and Asian sales have fared much better. U.S. revenue increased 20% in Q3 and was just about flat over the first three quarters. We see this as encouraging given that U.S. sales, which account for approximately 20% of total revenue, fell 17% in fiscal 2015 with one recent issue cited as a certain chain store delayed its screening program using EZ Detect. Asia saw revenue, which accounts for 30%+ of total sales, fall 2% in Q3 but increase by almost 2.5x YTD – the latter which includes the benefit of in easy comp in 1H 2016 due to the switch in distributors which caused a sales disruption in the prior year period.

On the operational front, BMRA is moving further towards the possibility of bringing their IBS test to market. In early calendar 2015 the company filed the first set of patents related to the product. Last month (March) the company announced that their international method and composition patent claims were reviewed by the International Search Authority (ISA) which found them to be novel and non-obvious (i.e. the claims are valid). Locking down the IP is an important initial step. Currently 8 patents are pending.

BMRA also 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. The company held a conference call in July 2015 where they released additional details about the test. 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 last September that they expect (assuming FDA acceptance) to pursue the de novo pathway and that the FDA has indicated that the risk profile of the test would likely not require a Class III (i.e. 'high risk') device designation. 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.

More compelling news came in 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.

In a (perhaps less than subtle) show of confidence in the future of inFoods and BMRA in general, earlier this month the company press-released that all of its board members plan to make open-market purchases of BMRA stock up to $500k in aggregate over the next 12 months.

Financials
Q3 revenue of $1.4 million was up 5% yoy, up 17% sequentially and 8% lower than our $1.5 million estimate. U.S. sales beat our estimate by about 33% while Asia and Europe came in lower by 31% and 12%, respectively.

OpEx were $614k, mostly inline with our $600k estimate and the $622k expensed in Q2. 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. In July 2015 BMRA 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 weak at 25.3%% - this compares to 32.7% in Q1 and 35.4% in Q2. BMRA cites product mix and higher than normal regulatory costs as the reason for dip in GM in Q3. 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 show a more determined turn around.

Q3 net loss and EPS were $135k and ($0.02), compared to our $63k loss and ($0.01) estimates. Net loss benefitted from $125k income tax benefit in the quarter as a result of a recent FASB accounting update.

Cash
The balance sheet remains solid. BMRA exited Q3 2016 with $859k in cash. Excluding changes in working capital, BMRA used $178k for operating activities in Q3. The balance sheet remains debt free. Book value at the end of Q3 stood at $5.4 million or approximately $0.71/share. We continue to believe that book value should put a floor on valuation of the company.

inFoods IBS Test

BMRA has provided some limited details about their IBS product including 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. Lab product is the first which they will pursue (regulatory hurdle is likely lower) and POC will follow
- 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
- 8 patents are currently pending. In March 2016 BMRA announced International Search Authority reviewed their international method and composition patent claims and found them to be novel and non-obvious (i.e. the claims are valid)
- FDA has indicated that the risk profile of the test would likely not require a Class III (i.e. 'high risk') device designation. BMRA expects to apply for the de novo route which 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

Market opportunity for the test;

- 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. BMRA recently noted that they are working with FDA on design of clinical trial(s).

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, and to a lesser extent rebounding revenue in the U.S., 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.

We look for 2016 revenue and EPS of $5.1 million (+4%) and ($0.05) and for this to grow to $8.4 million and $0.07 in fiscal 2020. We are maintaining our Buy rating. Our price target is $2.25/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, 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 $900k. Book value at the end of fiscal Q3 2016 stood at $5.4 million or approximately $0.71/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	13.5	20.4	9.6	1.3	15.5	2.7	2.7
CEMI	N/A	N/A	11.0	3.6	N/A	2.8	3.2
VIVO	24.0	22.0	13.3	5.1	13.0	4.5	4.3
ERB	N/A	N/A	N/A	2.8	822.0	2.0	2.5
ABAX	30.5	30.0	16.9	4.3	19.0	4.9	4.7
Average	**22.7**	**24.1**	**12.7**	**3.4**	**15.8**	**3.4**	**3.5**

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	-$0.66	-$1.21	$0.39	$2.45	$2.27	$2.35	**$2.31**

FINANCIAL MODEL

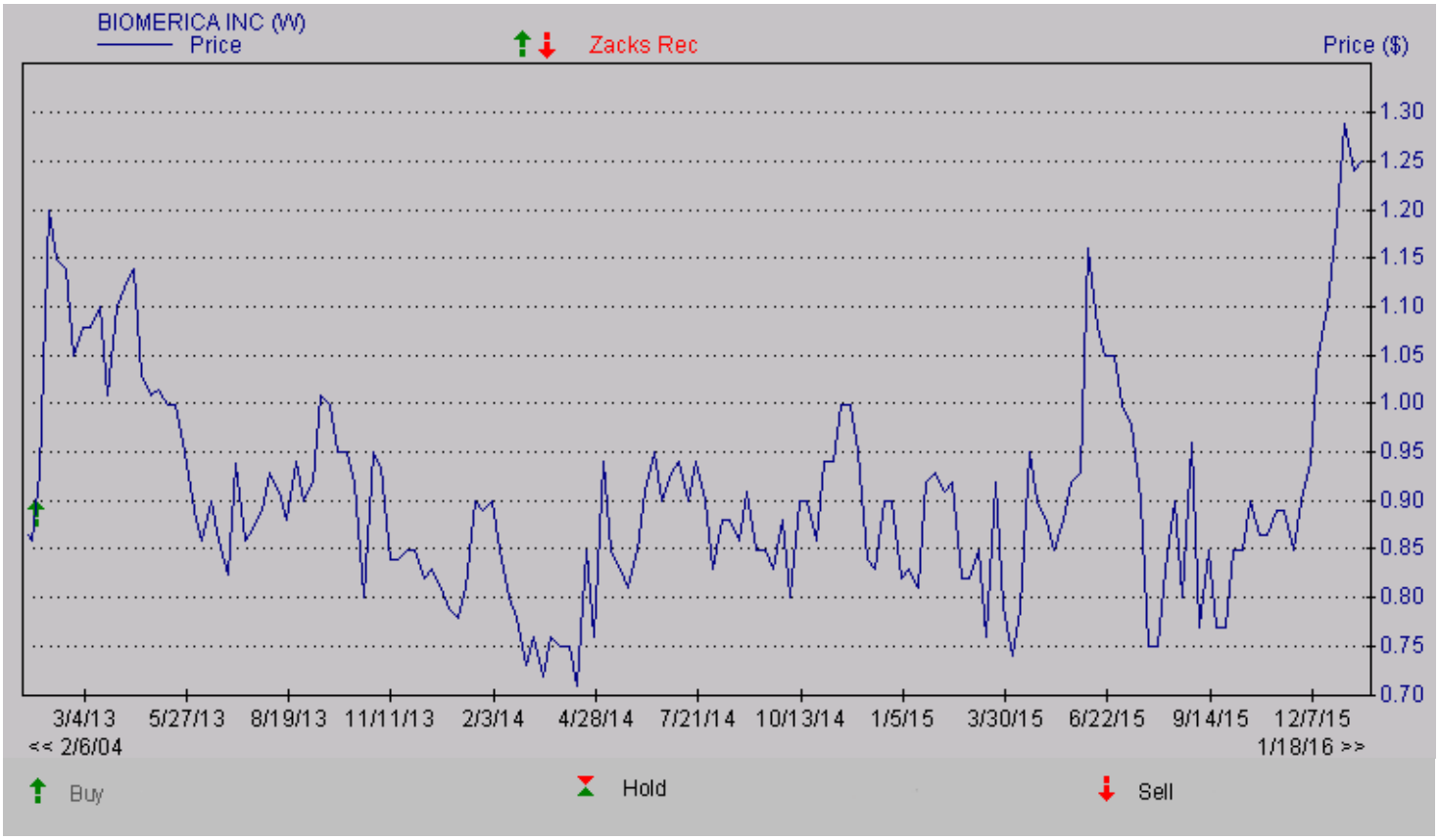
Biomerica Inc.

	2015 A	Q1A	Q2A	Q3A	Q4E	2016 E	2017 E	2018 E	2019 E
Total Revenues	$4,962.4	$1,287.0	$1,165.0	$1,361.6	$1,322.6	$5,136.2	$5,936.9	$6,436.8	$7,124.0
YOY Growth	*-3.1%*	*24.4%*	*2.8%*	*4.8%*	*-11.5%*	*3.5%*	*15.6%*	*8.4%*	*10.7%*
Cost of Goods Sold	$3,420.6	$865.6	$753.0	$1,017.1	$867.6	$3,503.3	$3,793.7	$3,939.3	$4,338.5
Gross Income	$1,541.8	$421.4	$412.0	$344.5	$455.0	$1,632.9	$2,143.2	$2,497.5	$2,785.5
Gross Margin	*31.1%*	*32.7%*	*35.4%*	*25.3%*	*34.4%*	*31.8%*	*36.1%*	*38.8%*	*39.1%*
SG&A	$1,478.8	$339.7	$391.6	$428.4	$396.8	$1,556.4	$1,668.3	$1,737.9	$1,852.2
% SG&A	*29.8%*	*26.4%*	*33.6%*	*31.5%*	*30.0%*	*27.1%*	*28.1%*	*27.0%*	*26.0%*
R&D	$733.6	$158.0	$230.2	$185.3	$175.0	$748.5	$728.0	$685.0	$657.0
% R&D	*14.8%*	*12.3%*	*19.8%*	*13.6%*	*13.2%*	*14.6%*	*12.3%*	*10.6%*	*9.2%*
Operating Income	($670.6)	($76.2)	($209.9)	($269.1)	($116.8)	($672.0)	($253.0)	$74.5	$276.2
Operating Margin	*-13.5%*	*-5.9%*	*-18.0%*	*-19.8%*	*-8.8%*	*-13.1%*	*-4.3%*	*1.2%*	*3.9%*
Total Other Income (Expense)	$24.1	$3.9	$14.0	$9.1	$8.5	$35.5	$14.2	$18.0	$24.0
Pre-Tax Income	($646.5)	($72.3)	($195.8)	($260.0)	($108.3)	($636.5)	($238.8)	$92.5	$300.2
Tax expense (benefit)	($315.0)	$0.0	($129.0)	($125.0)	$0.0	($254.0)	$0.0	$13.9	$45.0
Tax Rate	*0.0%*	*0.0%*	*65.9%*	*48.1%*	*0.0%*	*0.0%*	*0.0%*	*15.0%*	*15.0%*
Net Income	($331.5)	($72.3)	($66.8)	($135.0)	($108.3)	($382.5)	($238.8)	$78.7	$255.2
YOY Growth	*53.6%*	*-61.7%*	*-127.9%*	*-0.5%*	*111.0%*	*15.4%*	*-37.6%*	*-132.9%*	*224.4%*
Net Margin	*-6.7%*	*-5.6%*	*-5.7%*	*-9.9%*	*-8.2%*	*-7.4%*	*-4.0%*	*1.2%*	*3.6%*
EPS	($0.04)	($0.01)	($0.01)	($0.02)	($0.01)	($0.05)	($0.03)	$0.01	$0.03
YOY Growth	*49.9%*	*-61.9%*	*-128.2%*	*0.0%*	*110.6%*	*14.6%*	*-41.8%*	*-132.7%*	*220.9%*
Diluted Shares O/S	7,552	7,582	7,587	7,617	7,640	7,606	8,160	8,210	8,300

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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.

The current distribution is as follows: Buy/Outperform- 25.4%, Hold/Neutral- 49.3%, Sell/Underperform – 20.6%. Data is as of midnight on the business day immediately prior to this publication.