Zacks Small-Cap Research

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Biomerica Inc (BMRA-OTC)

BMRA: More Positive Clarity on InFoods FDA Pathway. Korean Licensing Agreement

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

Current Price (07/11/16)	$1.52
Valuation	**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, validation of intellectual property protection and initial regulatory guidance. FDA has indicated regulatory pathway could be relatively simple de novo. We expect to hear more details in near future on next steps. Recently signed licensing agreement for S. Korea, more could follow. Board recently began buying shares in open market as sign of confidence in inFoods' potential. Balance sheet remains solid.

SUMMARY DATA

52-Week High	**$1.80**
52-Week Low	**$0.75**
One-Year Return (%)	**52.00**
Beta	**0.20**
Average Daily Volume (sh)	**1,797**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$12**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**26**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-2.5**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**-15.2**
P/E using 2018 Estimate	**152.0**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Blend**
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 % **N/A**

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WHAT'S NEW……

FDA Determines InFoods is 'Nonsignificant Risk' Device: Eliminates Need for IDE Approval, Supports Expectation of De Novo Pathway…

Yesterday (July 11) Biomerica announced that the FDA has determined InFoods, the company's IBS test product candidate, is eligible to pursue 'nonsignificant risk' (NSR) clinical studies. While we were not surprised of the agency's determination, the news is meaningful as it means that BMRA can eliminate any need to file and have approved by the FDA an Investigational Device Exemption (IDE). Preparation and approval of IDE's can be a lengthy process - spanning anywhere from several months to a year or more, depending on the particular device and other circumstances.

NSR determination also means that InFoods should almost certainly not need to follow the FDA Premarket Approval (PMA) pathway, which is relatively lengthy and costly. While this was also a prior assumption of ours, having NSR classification now makes this all but a certainty. As there is no predicate for InFoods, we think de novo 510(k) (appropriate for novel low-risk products for which there is no predicate) is the likely U.S. regulatory clearance route that the candidate will follow.

FDA determines a device is of **'significant risk'** (SR) if it;

• Is intended as an implant and presents a potential for serious risk to the health, safety, or welfare of a subject;
• Is purported or represented to be for use supporting or sustaining human life and presents a potential for serious risk to the health, safety, or welfare of a subject;
• Is for a use of substantial importance in diagnosing, curing, mitigating, or treating disease, or otherwise preventing impairment of human health **and** presents a potential for serious risk to the health, safety, or welfare of a subject; or
• Otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.

If a device does not meet the definition above, then it is considered a **'nonsignificant risk'** device. Per FDA guidelines, NSR studies follow abbreviated requirements (as compared to SR devices) related to labeling, institutional review board (IRB) approval, informed consent, monitoring, records, reports, and prohibition against promotion. And unlike SR studies, there is no need to make progress reports or final reports to FDA. But, perhaps the greatest advantage is that NSR studies do not require the sponsor (i.e. BMRA) to file for or receive IDE approval prior to commencing the study. And while, of course, IRB approval will still be required prior to commencement of any NSR study, the IRB is not required to inform FDA in order for the study to be conducted.

IRB's will also make their own determination of whether a device is NSR or SR. But with FDA already determining InFoods meets their NSR definition, the IRB's can use this to facilitate (i.e. speed up and confirm) their own risk determination process.

Korean Market Licensing Agreement: Includes $1M Equity Investment at ~100% Premium…

In May BMRA announced consummation of an agreement whereby they granted Celtis Pharm Co. of S. Korea exclusive rights to market and sell InFoods in S. Korea. The deal calls for;

- Celtis to pay BMRA up to $1.25M in exclusivity fees based on "certain milestones including Biomerica's starting clinical trials in the United States, receipt of US FDA clearance and Celtis' first sales of IBS Products in Korea"

- If BMRA fails to obtain FDA clearance, $250k of the upfront exclusivity fee will convert into 83k BMRA common shares at $3/share

- Celtis to pay BMRA royalties in the "mid-teens" of sales of InFoods in S. Korea. Minimum royalty to maintain exclusivity status is $7.25M over five years (or longer if Korean regulatory approval is obtained prior to May 31, 2019) beginning when Korean regulatory clearance is obtained

- Upon achieving Korean regulatory clearance and commencement of commercialization, BMRA will sell InFoods to Celtis at cost plus (undisclosed) margin

- Celtis is responsible for funding and obtaining regulatory clearance for the S. Korean market

- Cetlis purchased 333k shares of BMRA common stock @ $3/share (in a private placement) - representing ~100% premium over the quoted market price the day prior to the licensing agreement announcement

The exclusivity agreement can be expanded to other territories in Asia if agreed upon by both parties. It spans five years plus an additional two years for Celtis to obtain Korean regulatory clearance, begins when InFoods is granted FDA marketing clearance. It is cancellable of BMRA has not obtained FDA clearance by December 31, 2017.

Our Comments…
Perhaps relating to significant potential for InFoods, while all details of this licensing agreement were not made public, from our experience this is a somewhat atypical type of deal in that it appears to significantly favor BMRA with most of the financial risk borne by Celtis…

- It implies $250k of the (up to $1.25M total) exclusivity fees was paid at signing, which even if InFoods fails to gain FDA clearance will be converted into BMRA at a ~100% premium to current market value

- Celtis purchased $1M of restricted BMRA common stock at a 100% premium - essentially paying BMRA another $500k upfront

- Celtis bears all financial risk of obtaining Korean regulatory clearance

- BMRA will receive a mid-teens royalty plus margin on sales of InFoods to Celtis

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. This was further supported when in July BMRA announced that FDA determined InFoods is eligible to pursue 'nonsignificant risk' clinical studies. 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).

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.

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

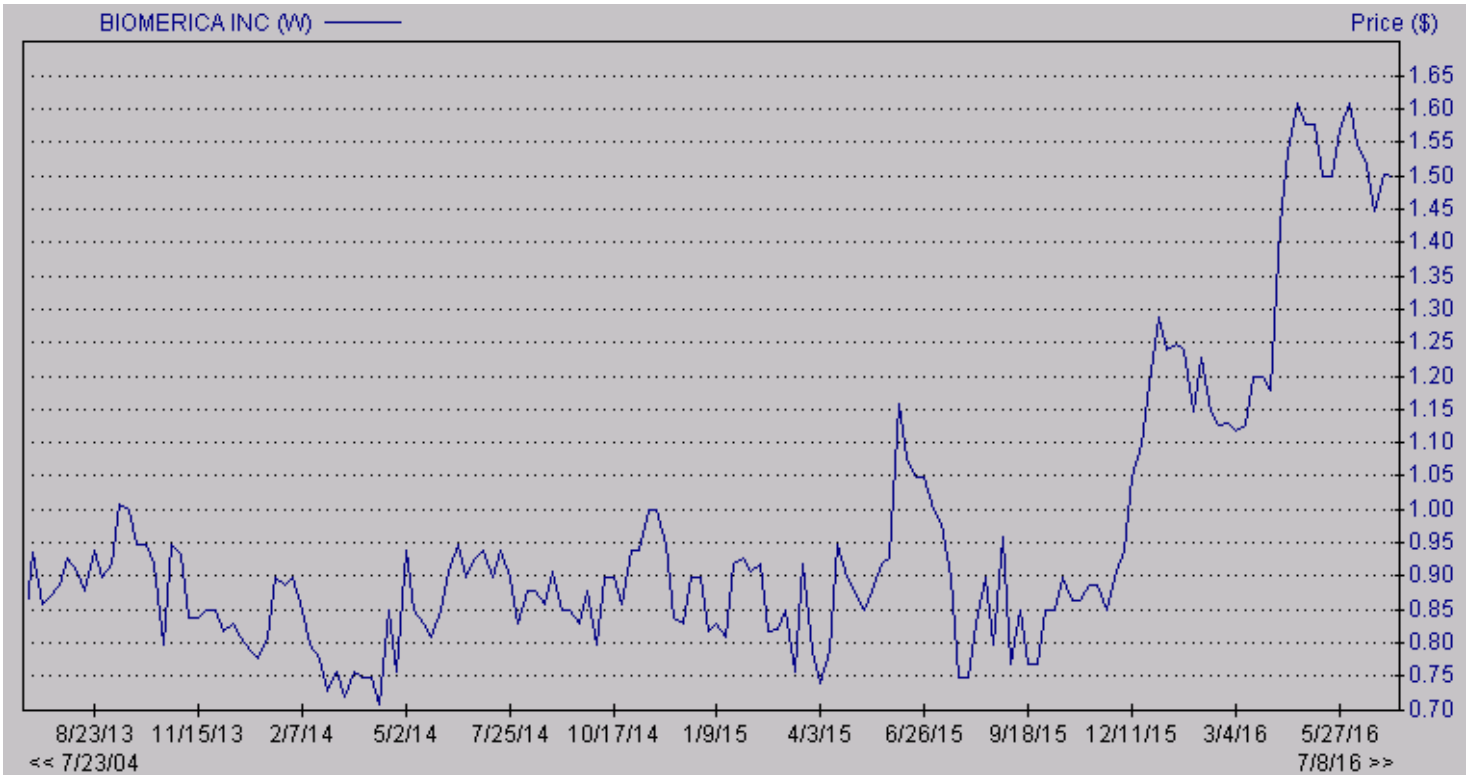
Biomerica Inc.

	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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