Zacks Small-Cap Research

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Biomerica Inc (BMRA-NASDAQ)

BMRA: Base Business Bounces Back, InFoods Continues to Attract Who's-Who of IBS

We use sum of the parts to value BMRA. Comparable P/S and P/B values the base business at $2.50/share. Applying 'upfront' multiple that Celtis paid for rights to InFoods in S. Korea to U.S. market values InFoods at ~$1.50/share. Sum of parts values BMRA at $4/share.

Current Price (10/19/16)	$2.75
Valuation	**$4.00**

OUTLOOK

BMRA 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 was 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. Additional disclosures regarding InFoods have prompted us to include it in our valuation. Our sum of the parts values BMRA at approximately $4/share. Additional progress towards locking down IP and in development and regulatory activities related to InFoods would likely push our valuation higher.

SUMMARY DATA

52-Week High	**$3.24**
52-Week Low	**$0.79**
One-Year Return (%)	**227.50**
Beta	**0.10**
Average Daily Volume (sh)	**11,816**
Shares Outstanding (mil)	**8**
Market Capitalization ($mil)	**$22**
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 (%)	**-3.6**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2017 Estimate	**N/A**
P/E using 2018 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**Above Avg.,**
Type of Stock	**Small-Growth**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Aug)	Q2 (Nov)	Q3 (Feb)	Q4 (May)	Year (May)
2016	1.29 A	1.17 A	1.36 A	1.33 A	5.14 A
2017	1.41 A	1.28 E	1.33 E	1.48 E	5.49 E
2018					5.79 E
2019					6.27 E

Earnings per Share

	Q1 (Aug)	Q2 (Nov)	Q3 (Feb)	Q4 (May)	Year (May)
2016	-$0.01 A	-$0.01 A	-$0.02 A	-$0.16 A	-$0.20 A
2017	-$0.01 A	-$0.03 E	-$0.02 E	-$0.02 E	-$0.08 E
2018					-$0.08 E
2019					-$0.06 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW……

Q1 2017 Results / Operational Update: *Base Business Bounces Back, InFoods Supported by IBS 'Dream Team'...*

Biomerica reported financial results for their fiscal third quarter ending August 31. Revenue surprised markedly on the upside relative to our expectations with each of the three significant territories (i.e. Europe, U.S. and Asia) contributing to the beat. And it wasn't just the top-line that impressed. Gross margin was at the widest level since fiscal Q1 2013 and operating expenses were meaningfully below our (per-revenue) estimate – and this is despite one-time expenses related to the recent NASDAQ uplisting that was captured in Q1 SG&A. The net result was positive variances of $195k in net loss and $0.02 in EPS.

Q1 revenue was up 10% yoy, 6% higher than fiscal Q4 2016 and about 12% better than our estimate. Total revenue was also the highest since Q4 2015. As noted, Europe, the U.S. and Asia, which combined account for more than 95% of the company's sales, all performed relatively well.

Sales in Europe, which has recently generated about 40% of the total top-line, came in at $554k – while this is down 11% from Q1 2016, it is better than every other quarter from the prior year including a 4% increase from Q4 (sequentially) and ahead of our $520k estimate. As we noted in our previous update, recent signs of European revenue stabilizing around ~$500k/quarter had us hopeful that this territory had potential to return to positive growth in the coming (i.e. current) year. The first quarter shows that Europe is off to a solid start in that regard. And as a reminder, management had previously mentioned that they hope to expand distribution to other countries in Europe – if that happens, European revenue could return to even more meaningful growth and continue to outpace our estimates.

Meanwhile, U.S. performance was somewhat similar to that of Europe – at $226k U.S. sales grew 3% sequentially and beat our $213k number by 6%. This was also higher than every other quarter in 2016 save one. But, the single digit beat and sequential growth comes after we had made downward revisions to our U.S.-related sales estimates due to underperformance over the prior several quarters. Nonetheless, the Q1 result, which is up 21% from the same period in 2016, is at least somewhat encouraging.

Asia, the other major territory, which accounts for approximately 40% of total sales, also came in relatively strong. Revenue from Asia was up 33% from $433k in Q1 2016, increased 12% sequentially from $512k in Q4 of last year and beat our $468k number by 23%. The $575k posted in the most recent quarter was also the highest revenue from Asia since Q4 2014.

The Q1 performance builds on the 71% Asian sales growth for the full year 2016. And while much of the prior year growth was related to an easy comp due to disruption in sales in 2015 from a switch in distributors, the most recent numbers may suggest Asia sales are back trending towards their historical peak of almost $2.8M. Noteworthy is that sales in Asia over the last six months of $1.087M are the highest over any two consecutive quarter period since the $1.601M generated in Q2 – Q3 2013 – which is the same year that Asian sales hit their all-time record. Given that Asian sales now account for approximately 40% of total revenue (up from 21% in 2015 and 25% in 2014), even incremental growth from current levels in this territory will have a meaningfully positive effect. We continue to model low double-digit annual growth in Asia sales over the next several years.

Financials

Q1 revenue of $1.41 million was up 10% yoy, up 6% sequentially and about 12% better than our $1.26 million estimate. European, U.S. and Asian sales beat our numbers by 7%, 6% and 23%, respectively. The other geographic territories, which combined account for less than 5% of total revenue, were largely inline with our estimates.

Q1 gross margin was 40.9% - well ahead of our 28% estimate and the 29.7% average throughout fiscal 2016. In fact, gross margin has not been at this level since Q1 2013. It is unclear what is behind the relative strength in GM – as such, this may be more timing or favorable product-mix related than anything necessarily fundamental that could be expected to persist. As such, we will continue to model full-year GM in the low 30%'s unless and until there is more to suggest that this is likely conservative.

Q1 OpEx were $643k, or 45.6% of revenue, compared to our $608k, or 48.1% of revenue. Q1 operating expenses would have been even lower if not for $45k in one-time NASDAQ uplisting fees. However, OpEx could increase considerably - which may be dependent on the pace of further development of the IBS test. While additional

substantive details of InFoods have become available over the last few months which has given us meaningfully greater confidence in the utility and potential regulatory and commercial success of the test (which is reflected in our recent upwardly revised price target), we will continue to refrain from modeling any clinical trial / regulatory related expenses or any forecasted revenue for the product until at least the IP threshold has been crossed, and likely, until there is more (comfortable) clarity surrounding the regulatory pathway (and related specifics) and requisite supporting clinical programs.

Q1 net loss and EPS were $55k and ($0.01), well ahead of our $250k and ($0.03) estimates.

Cash
The balance sheet remains solid. BMRA exited Q1 with $1.8M in cash and equivalents. Excluding changes in working capital. BMRA used $20k in cash for operating activities in Q1.

Operational Update
BMRA has made meaningful operational progress over the last several quarters – 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 recent financial performance has not been as strong as it had been in the past, it has improved and, importantly, BMRA continues to move down the road with what could potentially and eventually be their most significant product to-date.

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. In 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. Locking down the IP will be an important initial step. Currently 17 patents are pending. In June 2016 the international patent bureau effected an application communication date of May, 19 2016. Additional details regarding the specific test-related methodology is included in the patent application as are examples of how InFoods' methodology differs from prior art (in our opinion prior art is somewhat surprisingly lacking in robustness of statistical and other scientific methodology in regards to identification of IBS-related trigger foods).

Then July in the company announced that the FDA determined InFoods is eligible to pursue 'nonsignificant risk' (NSR) clinical studies - which means that BMRA can eliminate any need to file and have approved by the FDA an Investigational Device Exemption (IDE). Preparation and approval of which could have been lengthy.

Additional positive developments related to InFoods includes feedback from FDA indicating de novo 510(k) regulatory pathway should be acceptable and the July announcement that FDA has determined InFoods is eligible to pursue 'nonsignificant risk' (NSR) clinical studies (additional details below). And in May, BMRA penned a favorable licensing/distribution agreement for the S. Korean market (details below).

InFoods Development, Strategy Led By Dream Team…
BMRA also recently beefed up its board of directors and brought on a scientific advisory board as well as a strategic advisory board to help further guide their strategy related to the pipeline candidate. This includes the 'who's who' of IBS and GI in the U.S. and brings on significant resources and knowledge in medical diagnostics commercialization.

The **scientific advisory board includes** Dr. Doug Drossman, an expert in IBS who has authored several articles and publications on the disorder and who serves as the President of the Rome Foundation. The Rome Foundation is a leading (non-profit) organization focused on the diagnosis and treatment of GI disorders, including IBS. Drossman was a key addition to BMRA due not only to his background, experience and contacts related to IBS but also, in our opinion, the legitimacy that he provides for the potential for InFoods. In fact, Biomerica has noted that Dr. Drossman was skeptical about BMRA's technology until he fully reviewed it – and afterwards agreed to join the company's scientific advisory board. Dr. Drossman was instrumental in recruiting other members to the scientific advisory board, which has grown to now include five members. Other members, which also have extensive and pertinent experience in the GI space, include Dr. Li Chang, Dr. William Chey, Dr. William Whitehead and Dr. Anthony Lembo. Their bios are included in our Appendix.

In January 2016 Charles Carter, PharmD, was appointed as a senior advisor and in July Dr. Mark Sirgo was brought on to the board of directors – both Drs. Carter and Sirgo were associated with Salix Pharmaceuticals. 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. Sirgo served on Salix's board of directors. 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.

And more recently, Biomerica added a **strategic advisory board** with Ned Barnholt initiated in July as the first member. This board will be tasked with guiding BMRA's licensing and commercialization strategy for InFoods. Mr. Barnholt (full bio in Appendix) is chairman of KLA-Tencor, on eBay's board of directors and was former chairman, president and CEO of Agilent Technologies.

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

In July Biomerica announced that the FDA has determined InFoods 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

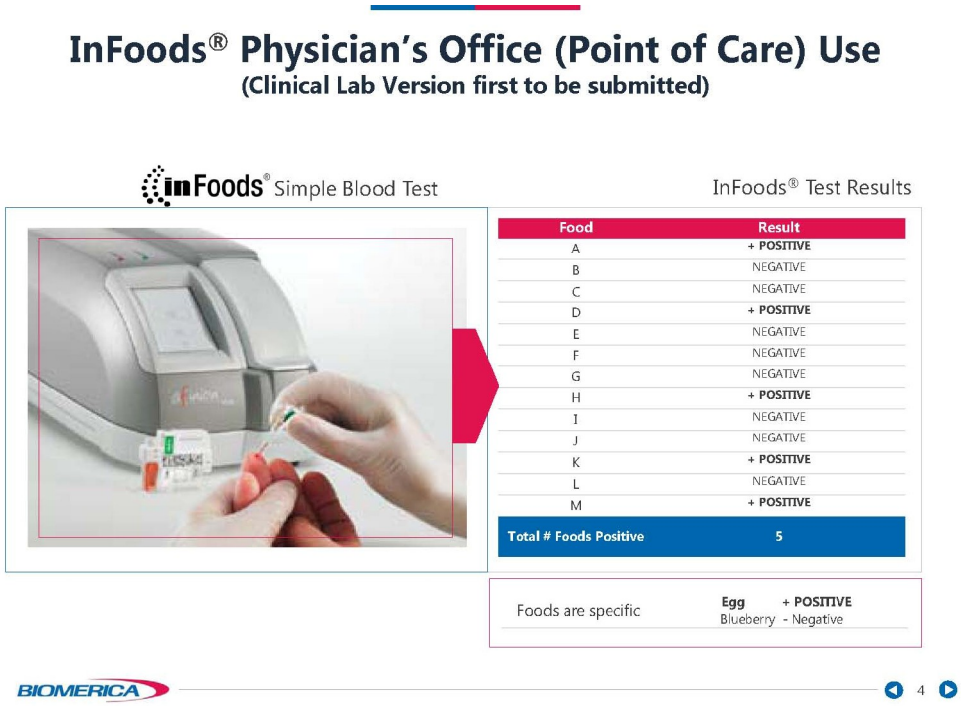
InFoods IBS Test

Important to understand about IBS and why we believe InFoods has so much potential is that while food is implicated as a trigger in exacerbating symptoms, not every IBS sufferers' symptoms are effected by the same foods. So it is not as simple as just identifying certain foods and eliminating those from anyone's diet that has the condition. As such, the heterogenous nature of IBS requires a diagnostic (i.e. InFoods) that accounts for varying and different causation between certain foods and an individuals' symptoms, or lack thereof.

Additional details about InFoods have been made public recently – this includes information gleaned from BMRA's patent applications as well as from the company's recent investor presentations.
Below we summarize what we believe are some of the most salient points regarding InFoods;

- blood test to identify certain trigger foods that may cause or exacerbate IBS symptoms
  - will be used only with individuals already identified with IBS symptoms
  - extensive analysis was done to rank the top several dozen foods most associated with exacerbating IBS
  - we expect somewhere in the range of 20 – 25 foods may be included on the initial panel
  - ELISA test quantifies food-specific IgG antibodies (i.e. 'signal scores') from individual IBS patients which are elicited as immune response
  - signal score 'cutpoints' for each food (and gender) were determined by comparing signal scores of IBS patients with those of non-IBS patients. Additional testing and analysis was done to refine these cutpoints, which represent the 90th and 95th percentiles. For each food, IBS subjects with resulting signal scores above these cutpoints are considered 'positive' for that particular food (i.e. that particular food exacerbates IBS)
  - results of the ELISA test provide a simple 'yes' or 'no' result indicating whether a particular person's IBS symptoms are being triggered by each of the foods on the panel
- InFoods is expected to 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
- expected to have utility for all forms of IBS (i.e. constipation (C), diarrhea (D) and mixed (M))
- 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
- in addition to the significant benefit of already established CPT coding is that it could be expected that patients would be tested up to several times over the course of a year, depending on changes in their diets

- 17 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 considerations related to InFoods: *Living with IBS is hell…*

- "Living with IBS is hell" – plug that into a Google search and it is apparent that the chronic disease symptoms and lack of treatment options leaves IBS sufferers feeling helpless and desperate for more effective options
- 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
  - Exact cause of IBS is not known although adverse reaction to certain foods is largely accepted as a significant contributor in many cases
  - Types of foods and food reactions do not appear to be homogenous from patient-to-patient (i.e. cocoa may trigger symptoms in one patient but not another). Therefore it is important to be able to identify which foods trigger symptoms in each individual patient
  - IBS drugs, such as Xifaxan, only treat the symptoms but not the underlying cause and have unwelcome side effects
  - GI doctors also often prescribe SSRI's off-label, which have shown to help regulate bowel flow – this again, illustrates how limited the treatment options are for IBS
  - Physicians have very limited tools to treat IBS – typical recommendation is for patients to (arbitrarily) begin eliminating certain foods from their diet and/or prescription of symptom-targeting drugs which often fail to provide significant relief, particularly over the long-term
- Win, win, win for patients, physicians and insurers. InFoods could benefit all major stakeholders. Physicians are frustrated with lack of treatment options. Patients feel helpless. Insurers are paying for relatively high cost drugs which do not address the underlying cause and therefore may be chronically prescribed

- Unlike many new medical technologies (drugs, devices and diagnostics) which offer only incremental benefit compared to an existing product and may be geared more towards profit than clinical outcome (and often require a lot of marketing to convince of the 'benefits'), InFoods could be a pioneer in providing a new level of relief for the IBS afflicted. And if InFoods can do that, it should require limited initial awareness-building before the test sells itself via demand-pull from physicians and patients

VALUATION

Previously we had not considered InFoods in our valuation of BMRA as we felt the limited available information about the test was not substantive enough for us to form even an initial opinion about its potential utility or eventual chance of regulatory and commercial success. But the additional public information that has recently become available including the general methodology employed in identifying and ranking specific trigger foods and statistically-driven rationale powering the output decision (i.e. 'yes' or 'no' for trigger food x) provides enough information for us to be at least comfortable with the soundness of the science that is employed and presumption that a similar test does not already exist (eventual patent grant should confirm this).

And while more anecdotal in nature, we think there are other reasons that support the proposition of the potential of InFoods. This includes the fact that Drs. Drossman and Sirgo (and others prominent in the field), all of which have significant experience in the IBS space, recently came onboard and presumably did so because they believe in the robustness of the science (including the non-publicly available information) behind InFoods, is a vote of confidence in the potential for success of the test. The addition of someone of Ned Barnholt's caliber to the newly formed strategic advisory board provides that much more credence to BMRA's pursuit.

The agreement with Celtis, which seems to favor BMRA, may also be interpreted as an "insider" liking what they see. The fact that, based on terms of the agreement that were made public, Celtis effectively made an upfront, nonrefundable $750k ($250k cash plus purchasing stock at $500k premium) payment to BMRA suggests the S. Korean company believes in the potential of InFoods.

We also think it is worth reiterating that there is a significant unmet need for an effective IBS treatment. As such, if InFoods can help to evenly modestly improve patient's lives, we think it could be wildly successful and rapidly adopted. The dearth of acceptable options to treat IBS is illustrated by IBSchek, a laboratory developed test from Commonwealth Labs (and which Valeant had at one point indicated they would acquire) which tests for two distinct antibodies associated with IBS. Despite it suffering from high false-negative rates (56%) and questionable practical utility (if someone has IBS, it's probably very apparent and they don't need a test to tell them) news of its launch received massive news coverage (including featured on CBS Nightly News) when it was introduced in 2015.

Recently updated methodology values BMRA at $4/share

We are now using sum of the parts to value BMRA; the base business (everything except InFoods) plus InFoods. We continue to value the base business using 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's base business is valued at approximately $2.50/share.

Base Business Comparable Multiples

Ticker	P/E (ttm)	P/E (FY1)	P/E (FY4)	P/Book	EV/EBITDA (ttm)	P/S (ttm)	P/S (FY1)
TRIB	29.7	19.4	N/A	1.5	11.2	1.6	1.6
OXFD	N/A	N/A	N/A	3.6	N/A	4.1	2.9
CEMI	N/A	N/A	0.0	7.6	N/A	4.0	4.7
ALR	19.3	17.4	13.5	2.8	16.5	1.5	1.5
VIVO	21.4	19.7	12.1	4.7	12.6	3.9	3.6
QDEL	N/A	N/A	N/A	3.6	48.0	3.7	3.0
ABAX	38.6	33.0	22.0	4.9	19.7	5.3	5.0
Average	**27.2**	**22.4**	**15.9**	**4.1**	**21.6**	**3.4**	**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	-$5.36	-$1.79	-$0.66	$2.83	$2.16	$2.13	**$2.37**

Value InFoods at ~$11M (~$1.50/share):
We think the Celtis agreement provides insight into the value of InFoods. As noted, we think the agreement was somewhat unusual and favored BMRA – the reason for which likely relates to the value that Celtis places on InFoods. While our methodology is admittedly back-of-the-envelope, it piggy-backs off of Celtis' assumed much greater insight they gleaned when they presumably had full access to data sheets and related information on InFoods during due diligence.

Prevalence of IBS in S. Korea is approximately 6% of the population, or ~3M people. Celtis effectively paid $750k upfront (nonrefundable) for rights to InFoods – which equates to approximately $0.25 per person in S. Korea with IBS. There are ~45M people in the U.S. with IBS – applying the same $0.25 per person multiple values InFoods at approximately $11M. While this is arguably conservative as it ignores all of Europe and any other parts of the world (ex-S. Korea), we think this is a fair representation of the current value of InFoods. Additional progress towards locking down IP and in development and regulatory activities should push value on InFoods higher from this estimated $11M current base.

Our sum of the parts of $2.50/share for the base business and $1.40/share for InFoods values the entire company at approximately $3.90 – we round to **$4/share.**

APPENDIX

Scientific Advisory Board

Dr. Douglas Drossman
Dr. Drossman is a veteran of over 50 FDA clinical trials and is the current president of the Rome Foundation, a leading international organization that provides support and guidance in the diagnosis and treatment of functional gastrointestinal disorders. The Rome Foundation is responsible for creating the Rome process, and the criteria developed through this process are the most widely employed in clinical trials related to IBS.

Dr. Lin Chang
Director, Digestive Health and Nutrition Clinic UCLA GI Fellowship Training Program and Professor, Digestive Diseases/Gastroenterology. Dr. Chang has significant experience with pharmaceutical and healthcare companies as she has been an advisor or consultant to over 32 major pharmaceutical companies, including GlaxoSmithKline, Novartis, Merck, Allergan, Takeda, Salix, Synergy, Johnson & Johnson, Entera Health, and Ardelyx. Her experience with the FDA includes serving on the Gastrointestinal Drugs Advisory Committee of the FDA 2005-2010 (Chair 2009-2010) and again 2015-2019 as well as working as a FDA Special Government Employee from 2009-2013.

Dr. William Chey
Professor of Internal Medicine, Director of the GI Physiology Laboratory, and Director of Medical Services for the Michigan Bowel Control Program at the University of Michigan. Dr. Chey has also worked with many major pharmaceutical and healthcare companies as an advisor or consultant, including Entera Health, Ironwood, Nestle, Proctor and Gamble, Salix, and Takeda. He is the Chair of the U.S. Scientific Advisory Board at SmartPill Corporation and a member of the Clinical Advisory Board at Synthetic Biologics.

Dr. William Whitehead
Director of the Center for Functional GI & Motility Disorders and Professor of Medicine Adjunct Professor of OB-GYN at University of North Carolina School of Medicine. He has worked on 29 NIH grants (19 as principal investigator, 10 as co-investigator) and has been continuously funded by NIH since 1977. On behalf of the International Foundation for Functional Gastrointestinal Disorders, he organized two international consensus conferences on the treatment of fecal incontinence (1999 and 2002) and led a workshop on design of treatment trials for pharmaceutical companies, academic investigators, the NIDDK, and the FDA for 8 years. As a consultant, he has worked with large pharmaceutical companies on clinical trial design, including Takeda, Sucampo, Ironwood, Forest, Ono, and McNeil.

Dr. Anthony Lembo
Director of the GI Motility Laboratory at the Beth Israel Deaconess Medical Center's (BIDMC) Division of Gastroenterology in Boston, MA and as an Associate Professor of Medicine at Harvard Medical School. Dr. Lembo completed his residency and GI Fellowship at UCLA Medical Center. He is an accomplished expert in afflictions of the gastrointestinal tract and IBS. He divides his time between clinical medicine and research at Beth Israel Deaconess Medical Center in Boston. He has authored numerous original clinical studies and other research articles related to IBS.

Strategic Advisory Board

Ned Barnholt
Currently chairman of the KLA-Tencor Corporation and serves on the board of directors of eBay and Adobe. He is the former chairman, president, and chief executive officer of Agilent Technologies, a leading company in life sciences, diagnostics and applied chemical markets. Mr. Barnholt led the Agilent Technologies spin-off of Hewlett-Packard Company which broke records as the largest initial public offering (IPO) in Silicon Valley history at the time of the IPO (US $2.1 billion).

FINANCIAL MODEL

Biomerica Inc.

	2016 A	Q1A	Q2E	Q3E	Q4E	2017 E	2018 E	2019 E	2020 E
Total Revenues	$5,139.8	$1,410.1	$1,275.7	$1,333.3	$1,467.4	$5,486.6	$5,948.1	$6,444.6	$6,896.5
YOY Growth	*3.6%*	*9.6%*	*9.5%*	*-2.1%*	*10.6%*	*6.7%*	*8.4%*	*8.3%*	*7.0%*
Cost of Goods Sold	$3,615.8	$833.1	$903.2	$917.3	$990.5	$3,644.2	$4,009.0	$4,247.0	$4,517.2
Gross Income	$1,524.1	$577.0	$372.5	$416.0	$476.9	$1,842.4	$1,939.1	$2,197.6	$2,379.3
Gross Margin	*29.7%*	*40.9%*	*29.2%*	*31.2%*	*32.5%*	*33.6%*	*32.6%*	*34.1%*	*34.5%*
SG&A	$1,570.7	$418.3	$408.2	$413.3	$435.8	$1,675.7	$1,784.4	$1,894.7	$1,979.3
% SG&A	*30.6%*	*29.7%*	*32.0%*	*31.0%*	*29.7%*	*30.5%*	*30.0%*	*29.4%*	*28.7%*
R&D	$780.3	$224.2	$198.0	$207.0	$211.0	$840.2	$812.0	$788.0	$771.0
% R&D	*15.2%*	*15.9%*	*15.5%*	*15.5%*	*14.4%*	*15.3%*	*13.7%*	*12.2%*	*11.2%*
Operating Income	($826.9)	($65.6)	($233.7)	($204.3)	($169.9)	($673.6)	($657.3)	($485.1)	($371.0)
Operating Margin	*-16.1%*	*-4.7%*	*-18.3%*	*-15.3%*	*-11.6%*	*-12.3%*	*-11.1%*	*-7.5%*	*-5.4%*
Total Other Income (Expense)	$31.0	$10.2	$3.5	$3.0	$3.0	$19.7	$18.0	$24.0	$25.0
Pre-Tax Income	($796.0)	($55.4)	($230.2)	($201.3)	($166.9)	($653.9)	($639.3)	($461.1)	($346.0)
Tax expense (benefit)	$703.8	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*-88.4%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($1,499.8)	($55.4)	($230.2)	($201.3)	($166.9)	($653.9)	($639.3)	($461.1)	($346.0)
YOY Growth	*352.4%*	*-25.3%*	*121.0%*	*5.4%*	*-70.6%*	*-56.4%*	*-2.2%*	*-27.9%*	*-25.0%*
Net Margin	*-29.2%*	*-3.9%*	*-18.0%*	*-15.1%*	*-11.4%*	*-11.9%*	*-10.7%*	*-7.2%*	*-5.0%*
EPS	($0.20)	($0.01)	($0.03)	($0.02)	($0.02)	($0.08)	($0.08)	($0.06)	($0.04)
YOY Growth	*348.0%*	*-31.3%*	*109.2%*	*4.3%*	*-70.4%*	*-59.3%*	*-2.6%*	*-28.7%*	*-25.0%*
Diluted Shares O/S	7,626	8,170	8,175	8,175	8,180	8,175	8,210	8,300	8,300

Brian Marckx, CFA

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