Zacks Small-Cap Research

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Biomerica Inc (BMRA-NASDAQ)

BMRA: Q1 Results Fairly Solid. Novel H. Pylori Test Piques Our Interest

We use sum of the parts to value BMRA. Comparable P/S and P/B values the base business at ~$2.60/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 $4.00/share.

Current Price (10/19/17)	$2.80
Valuation	**$4.00**

OUTLOOK

Q1 2018 revenue was fairly solid as compared to recent history and up in the low single-digits on a yoy basis. And based on the earnings release, Q1 revenue would have been even higher had it not been for late shipments of certain product materials – that should benefit Q2's top-line. Also encouraging as it relates to the Q1 numbers was gross margin returning to the 35%+ level and a moderating of opex – the net result was sequential improvement in operating loss, which also came in a hair better than what we were modeling.

The company remains committed to expanding their product menu. While clearly the single major focus is successful development of InFoods, other high-potential projects continue in parallel. Another program, related to a novel h. pylori diagnostic was the latest to be divulged. Given BMRA's relatively tiny size ($24M MC, ~$6M annual revenue), capturing as little as one-quarter of one percent of the U.S. non-invasive h. pylori market (or ~$1.5M) would be highly significant for the company. We hope to know more about the test in the non-too-distant future which may help in assessing potential competitiveness to currently available diagnostics as well as provide some useful data points for modeling purposes.

SUMMARY DATA

52-Week High	**$2.99**
52-Week Low	**$1.53**
One-Year Return (%)	**-1.08**
Beta	**-0.69**
Average Daily Volume (sh)	**9,157**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$24**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**1**
Insider Ownership (%)	**26**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-2.9**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**N/A**
P/E using 2019 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)
2017	1.41 A	1.43 A	1.50 A	1.45 A	5.79 A
2018	1.45 A	1.51 E	1.62 E	1.60 E	6.18 E
2019					6.70 E
2020					7.17 E

Earnings per Share

	Q1 (Aug)	Q2 (Nov)	Q3 (Feb)	Q4 (May)	Year (May)
2017	-$0.01 A	-$0.02 A	-$0.04 A	-$0.04 A	-$0.11 A
2018	-$0.02 A	-$0.03 E	-$0.03 E	-$0.03 E	-$0.12 E
2019					-$0.08 E
2020					-$0.01 E

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

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WHAT'S NEW……

Q1 2018 Results: *Fairly Solid, Timing Issue Should Benefit Q2. Looking Forward to Details on H. Pylori Test...*

Biomerica reported financial results for their fiscal 2018 first quarter ending August 31, 2017. While a slight miss to our number and flattish from fiscal Q4 2017, revenue was nonetheless fairly solid as compared to recent history and up in the low single-digits on a yoy basis. And based on the earnings release, Q1 revenue would have been even higher had it not been for late shipments of certain product materials which resulted in delayed revenue recognition – that should benefit Q2's top-line. Also encouraging as it relates to the Q1 numbers was gross margin returning to the 35%+ level (up more than 500 bps from Q4, and wider than 10 of the last 12 quarters) and a moderating of opex – the net result was sequential improvement in operating loss, which also came in a hair better than what we were modeling.

And while revenue from all three of BMRA's largest territories, which together account for over 90% of total sales, were below our respective estimates, none of the misses were overly significant. Part of that trio is Asia, which has long been the company's most important territory and currently accounts for more than 40% of total sales. Importantly, revenue from this territory continued its streak of yoy growth (now at five consecutive quarters) which was the main catalyst in driving the top line.

Perhaps the most disappointing showing came from the U.S. – while sales were up a very healthy 43% from Q4 2017, this was down more 17% from Q1 of the prior year. Domestic sales have struggled to gain much traction. Despite accounting for only about 15% of total sales, softness from this territory has noticeably hampered total revenue growth.

Meanwhile, European revenue only fell in the mid-single digits compared to both the prior year and prior quarter periods. We continue to like the chances for OUS sales to return to sustainable growth as a result of BMRA's focus on growing the international business via expansion of their distribution footprint. In August they announced an agreement with a "multinational pharmaceutical company" (with annual revenue of $1.4B and 11k+ employees) to distribute one of Biomerica's POC products in Mexico and also indicated that they continue to look for additional distribution partnerships.

Revenue

Q1 revenue of $1.45M was up 2% yoy (from $1.41M), flat sequentially and about 5% shy our $1.52M estimate. U.S. revenue, at $187k was down 17% yoy and well below our $226k estimate. While somewhat soft and underwhelming, perhaps more encouraging is that Q1 domestic sales were better than two of the last three prior quarters, including a 43% improvement from Q4 2017. But had U.S. maintained their 2016 average ($250/qtr) and the aforementioned materials shipment issue not delayed additional sales, total company-wide revenue might have shown growth in the double-digits on both a yoy and sequential basis.

Revenue from Asia was $620k in Q1, representing 8% growth yoy but a similar percentage contraction from Q4. As we have noted in the recent past, while Asia has been a territory which has historically experienced relatively high short-term sales volatility, longer-term trends continue to point towards regular revenue growth. This is evident when comparing Q1's 8% sequential contraction (i.e. high short-term volatility) to 31% growth of the combined most recent four quarters (i.e. longer-term growth trend). Relatively robust and consistent revenue growth from Asia has resulted in this territory becoming the greatest contributor to total revenue as well as the most significant catalyst to recent total top-line growth.

BMRA generated just $1.0M in sales (~21% of total revenue) from Asia in 2015 - this grew 71% to $1.7M in 2016 and another 39% to $2.4M in 2017. In fact, Asia was effectively the only reason why total revenue posted positive growth in 2016 and is credited with almost 90% of the topline growth in 2017. And among the territories which did post positive revenue growth in Q1 2018, Asia contributed 42% of the total growth. Given the outsized contribution from Asia (which now accounts for 43% of total revenue) 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 couple of years.

Europe was also a bright spot in 2017, although not anywhere near that of Asia. Nonetheless revenue grew 3% in 2017 – which was a welcome result, particularly given the 20% battering that this territory endured in the prior year. Q1 2018 sales slid 4% on a yoy basis and 6% sequentially – the latter which also reflected the difference to our estimate. Europe accounts for about 37% of total sales, making it the company's second most important market and causing any meaningful variability to have a significant influence on overall financial performance. While BMRA

has always kept operating metrics close to the chest, making forecasting territorial-level revenue a challenge, we like recent trends in European revenue as well as certain macro fundamentals which could further benefit sales. This includes the implementation by European regulators of stricter regulatory and oversight of medical devices and diagnostics – which could slow the entry of competitive products, at least for the first few years.

Relative to the U.S., as noted, domestic sales have struggled to gain traction for some time now. U.S.-related revenue peaked in 2014 at $1.26M and have slid ever since - falling 17% in 2015, 4% in 2016 and were down another 12% in 2017. Q4 2017 was exceptionally weak so the 43% sequential growth through Q1 2018 was encouraging, although was facilitated by the easy comp. While we continue to model roughly flattish U.S. sales from the company's currently commercialized product portfolio, that would almost certainly change if and when InFoods, the company's novel IBS product, gains FDA regulatory clearance and launches. Another possible contributor could be a new h. pylori test, which is currently under development (and which we discuss in more detail below).

Gross Margin, Operating Expenses

Despite contracting from 40.9% in Q1 2017, we'd characterize gross margin as a highlight. At 35.6%, it was up 530 basis points from Q4 2017, wider than 10 of the last 12 quarters and slightly better than our 34.5% estimate. We continue to expect to see additional benefits in margin with sales growth. As a reminder, BMRA's gross margin was almost 38% at historical annual sales of $6M – so while territorial sales-mix will also likely influence margins, this indicates our gross margin estimates (including 36% on $6.2M in sales in 2018) could prove conservative.

Q1 OpEx was $741k, or 51% of revenue, largely inline with our $771k and 51% estimates. Both R&D and SG&A expense were almost dead-on with their respective quarterly averages during 2017. Operating expenses have trended meaningfully higher versus 2016, however – some of this difference undoubtedly relates to lower revenue throughout that year (i.e. revenue levels have some influence on sales/mktg related spend). But also, some incremental headcount additions as well as activities related to InFoods development likely contributed to OpEx recently moving higher. But as we have noted in the past, given management's history of diligence on cost control coupled with expectations of continued topline growth, we continue to look for improved operating scale in future years - particularly if and when InFoods is commercialized.

We reiterate, however, that while our model reflects an expectation of incremental InFoods-related development and regulatory expenses, we continue to refrain from modeling any potential revenue for the product due to significant uncertainties related to development outcomes and regulatory deliverables including requisite clinical trial programs (including scope, size, design and outcome measures) and additional validation of the performance, replicability and clinical utility of the product. We will, however, continue to revisit this assumption on a regular and ongoing basis and consider updates to our model (potentially including InFoods-related revenue contribution) with additional and substantive development and/or regulatory progress.

Cash

Cash balance at the close of Q1 was $1.1M, down slightly from $1.2M at the end fiscal 2017 (i.e. May 31, 2017). Cash used in operating activities was $125k ($141k ex-changes in working capital). Another $20k was used for the purchase of certain PP&E. On June 30, 2017 Biomerica filed an S-3 registration statement with the SEC, registering for sale (up to) $45M in common stock. While the shelf/prelim prospectus includes the typical generic language of "for working capital and general corporate purposes" as it relates to the use of proceeds, if BMRA does conduct a secondary offering we think proceeds would almost certainly be mostly targeted towards advancement and further development, including clinical validation, of InFoods.

Additional, non-dilutive funds, could come from BMRA's agreement with Celtis Pharm Co. of S. Korea which calls for that company to pay Biomerica 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". This agreement is cancellable if BMRA has not obtained FDA clearance/approval of InFoods by December 31, 2017. But while it is highly unlikely that InFoods will be U.S. regulatory greenlighted by then, we note that this date can be extended if agreed upon by both parties.

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 (although has recently returned to near-historical highs), it has greatly improved (particularly in Asia) and, importantly, BMRA continues to move down the road with what could potentially and eventually be their most significant product to-date.

Novel H. Pylori Test Begins Clinical Studies…

The company remains committed to expanding their product menu. While clearly the single major focus is successful development of InFoods, other high-potential projects continue in parallel. Another program, related to a **novel Helicobacter pylori (h. pylori) diagnostic** was the latest to be divulged. BMRA already has several h. pylori tests in their product catalog including ELISA blood antibody tests, a rapid antibody test for the OTC market and a rapid stool-based antigen test for the professional POC market.

H. pylori is a gram-negative bacteria found in the stomach. While it is relatively common – as much as 50% or more of the world's population are infected with the bacteria – most people do not exhibit symptoms. But, of the 15% - 20% that do have a reaction, symptoms can include stomach pain, reflux, nausea and bloating. H. pylori is associated increased risk of ulcers and is the strongest known risk for developing gastric cancer. Additionally, length of exposure to h. pylori is positively correlated to the risk of gastric cancer. Once diagnosed, standard therapy consists of proton pump inhibitors and certain antibiotics.

In typical BMRA fashion, the company disclosed little about their new product candidate but did note in their September 12, 2017 press release that clinical studies have been initiated for their new and proprietary h. pylori test which "is designed to increase the sensitivity and specificity of H. pylori testing and monitoring of treatment." It goes on to mention that the studies are being done in collaboration with the University of Southern California and Vanderbilt University, along with an unnamed European University. Biomerica is ballparking 6 – 12 months for the clinical studies, following which analytical studies will be conducted. BMRA anticipates an eventual application seeking U.S. regulatory clearance will follow FDA's 510(k) pathway.

Additional details about the study, titled *Specimen Collection Study for H. Pylori Testing in Patients With Dyspepsia*, are listed on clinicaltrials.gov (ID: NCT02970110, link: http://bit.ly/2gRuwLD). Principal investigators are Dr. Anthony Lembo (Harvard Medical) and Dr. Douglas Morgan (Vanderbilt Medical). Dr. Lembo is also a member of BMRA's Scientific Advisory Board and a recognized expert in GI disorders. Per clinicaltrials.gov, the study, which will be conducted at a minimum of two sites, will acquire human specimens from patients (n=200) undergoing endoscopy with gastric biopsy for the diagnosis of active h. pylori infection. The biopsy tissue (sampled from the stomach) will be evaluated with histology and rapid urease test (or RUT, a commonly used test which identifies the presence of urease, an enzyme secreted by h. pylori). The study design also notes that a **stool sample will be obtained by the participants prior to undergoing endoscopy** and that "results and specimens will be used in a future clinical trial [i.e. "analytical studies" referenced in BMRA's PR] of a non-invasive in vitro diagnostic assay for the detection of H. pylori antigen". **Which we think suggests that BMRA's novel h. pylori test will be stool-based.**

Currently there are several methods to test for the presence of h. pylori. This includes histology, RUT and culture – all of which require invasive biopsy sampling, and non-invasive methods including urea breath test (UBT), serology and stool antigen tests (SAT). There are advantages and disadvantages of each. This includes expense and discomfort of invasive testing and lower accuracy of non-invasive serology testing. Below is a summary (compiled from data of several studies) of the different tests and their relative advantages and disadvantages – the table is from a study by JY Lee and N Kim, published in the January 2015 issue of Annals of Translational Medicine.[1]

[1] Ju Yup Lee and Nayoung Kim. Diagnosis of Helicobacter pylori by invasive test: histology. Ann Transl Med. 2015 Jan; 3(1): 10.

Diagnostic tests for the detection of *H. pylori* infection (2,15-17)

Test	Sensitivity	Specificity	Advantages	Disadvantages
Noninvasive				
Serology	76-84	79-90	Widely available, inexpensive	Positive result may reflect previous rather than current infection, not useful after treatment
Urea breath test	>95	>95	High negative and positive predictive values, useful before and after treatment	False-negative results possible in the presence of PPIs or with recent use of antibiotics of bismuth preparations, considerable resources and personnel required to perform test
Stool antigen test	96	97	High negative and positive predictive values, useful before and after treatment	Process of stool collection may be distasteful to patient, false-negative results possible in the presence of PPIs or with recent use of antibiotics or bismuth preparations
Invasive				
Histology	95	99	Excellent sensitivity and specificity, especially with special and immune stains, provides additional information about gastric mucosa	Expensive (endoscopy and histopathology costs), interobserver variability, accuracy affected by PPI and antibiotics use, requires trained personnel
Rapid urease test	90	93	Rapid results, accurate in patients not using PPIs or antibiotics, no added histopathology cost	Requires endoscopy, less accurate after treatment or in patients using PPIs
Culture	58.1	100	Specificity 100%, allows antibiotics sensitivity testing	Variable sensitivity; requires trained staff and properly equipped facilities, expensive

Our Comments: Currently available SAT tests are generally considered highly accurate, although as the table illustrates, there are drawbacks including that the use of PPIs, antibiotics or recent bismuths can affect sensitivity. We will be interested to hear future updates on the progress of the clinical and validations studies and more details about the test under development. Learning more about the novel nature, and how it differs from currently available SATs, will be of particular interest to us. We think that if the test was designed to address one or more of the shortcomings of current SATs – such as, for example, being unaffected by PPIs (with no meaningful compromise to accuracy) or even improving on accuracy, that that may provide for significant differentiation.

Approximately six million non-invasive h. pylori tests are performed each year in the U.S. – if we assume $100/test, that calculates to a domestic market size of around $600M. And this is expected to grow given increasing prevalence of h. pylori and a greater shift from direct (i.e. invasive) to non-invasive methods – which could be further catalyzed with the advent of novel technologies (potentially including BMRA's test) addressing some of the drawbacks of currently available tests.

Given BMRA's relatively tiny size ($24M MC, ~$6M annual revenue), capturing as little as one-quarter of one percent of the U.S. non-invasive h. pylori market (or ~$1.5M) would be highly significant for the company. One percent market share could mean doubling of revenue from current levels. We hope to know more about the test in the non-too-distant future which may help in assessing potential competitiveness to currently available diagnostics as well as provide some useful data points for modeling purposes.

InFoods

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 2016 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. BMRA notes in their 2017 10-K that they have filed 22 provisional patent applications related to new tests to identify possible triggers for causing specific symptoms. 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).

Additional positive developments related to InFoods includes feedback from FDA indicating de novo 510(k) regulatory pathway should be acceptable and the July 2016 announcement that FDA determined InFoods is eligible

to pursue 'nonsignificant risk' (NSR) clinical studies (additional details below) - 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. And in May of that same year, 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 2016 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 traveler's diarrhea caused by E. coli as well as for overt 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 2016 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 2016 Biomerica announced that the FDA determined InFoods is eligible to pursue 'nonsignificant risk' (NSR) clinical studies. While we were not surprised of the agency's determination, the news was 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 product candidate 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: Included $1M Equity Investment at ~100% Premium…

In May 2016 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 if BMRA has not obtained FDA clearance by December 31, 2017, or another date agreed upon between BMRA and Celtis.

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 that even if InFoods fails to gain FDA clearance that $250k of the (up to $1.25M total) exclusivity fees will be converted into BMRA at a ~100% premium to then-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, the same foods do not affect every IBS sufferer the same (i.e. different people may have different trigger 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 and can be used in combination with IBS drugs. 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 more than once (i.e. 2 - 3x) 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 2016 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

Analysis of IBS Drugs Indicates High Unmet Need For Alternative, More Effective Therapies

Unmet Need for IBS Relief Highlighted By IBS Drugs' Low Effectiveness, Low FDA Approval Hurdle

The U.S. market for IBS drugs is approximately $1B+, almost twice the size of what it was only just a few years ago. The market is likely to continue to grow at a rapid pace, largely driven by new drugs that have either recently come to market or that are expected to do so in the near-term. But while the number of drugs available to treat IBS and related expenditures continues to grow, their relative ineffectiveness in providing relief has not significantly changed.

Today, the prescription IBS drug market is mostly concentrated across four products; Linzess (Allergan) and Amitiza (Takeda) for IBS-C, and Xifaxan (Valeant) and Viberzi (Allergan) for IBS-D. No drug is approved in the U.S. for the treatment of IBS-M. All of these gained FDA approval for their respective IBS indications since 2012 and two, Xifaxan and Viberzi, were approved for the U.S. market in May 2015 and launched later that year.

Low FDA Approval Hurdle…
FDA has clearly recognized the seeming futility drugmakers have experienced in their quest to develop a therapy that provides significant and long-term relief of IBS. This is evidenced by the low bar the U.S. regulatory agency has recommended in terms of efficacy endpoints that novel drugs are assessed against in order to determine

whether they will be approved for sale. We note that while FDA updated their recommendations for evaluation of novel IBS drugs in 2012 to better assess their effectiveness in addressing symptoms of IBS, the effectiveness hurdle (i.e. improvement vs. placebo) remains low.

The table below describes the pre-updated primary endpoints that have been used in many IBS drug trials. FDA updated their guidelines as they felt that while the prior endpoints could capture the direction of change, they did a poor job of providing useful information of the effect of treatment on sign and symptoms of IBS.

Prior IBS Endpoint Guidelines

Drug and Indication	Primary Endpoint	Questions (Single-Item) Used to Assess Efficacy	Responses
Alosetron — IBS-D[1]	Adequate relief	*In the past 7 days, have you had adequate relief of your IBS pain or discomfort?*	Binary (Yes/No)
Tegaserod — IBS-C[2]	Satisfactory relief	*Did you have satisfactory relief of your overall IBS symptoms during the last week?*	Binary (Yes/No)
		Did you have satisfactory relief of your abdominal discomfort or pain during the last week?	Binary (Yes/No)
	Subject Global Assessment of Relief (SGA)	*Please consider how you felt during the past treatment period in regard to your IBS, in particular your overall well-being, and symptoms of abdominal pain/discomfort and altered bowel habit. Compared to the way you usually felt before entering the trial, how would you rate your relief of symptoms during the past week?*	5-Point Likert scale
Lubiprostone — IBS-C[3]	Modified version of the SGA	*How would you rate your relief of IBS symptoms (abdominal discomfort/pain, bowel habits, and other IBS symptoms) over the past week compared with how you felt before you entered the trial?*	7-Point Likert scale

SOURCE: US Dept HHS, FDA, CDER. IBS – Clinical Eval of Drugs. May 2012

The updated recommended guidelines are more defined in terms of assessment of the effect on symptoms and specifically cites a defecation component and an abdominal pain component. For IBS-C drugs, recommendation is that defecation is assessed by stool frequency (number of complete bowel movements per week) while IBS-D drugs be assessed by stool consistency (based on Bristol Stool Form Scale). The pain component, for both IBS-C and IBS-D, can be based on an 11-point numeric scale.

The table below describes the updated (i.e. 2012) recommended guidelines for primary endpoints of IBS-C and IBS-D investigational drugs. Here we can see that the definition of treatment 'response' in these updated guidelines is more directly tied to IBS symptoms (as compared to prior guidelines). But also, the 'response' thresholds are arguably meek (and, in the case of the pain measure, potentially still fraught with subjectivity).

Note that 'response' related to abdominal pain is a decrease of 30% or more (in weekly average worst pain) in the past 24 hours. Weekly stool consistency 'response' is reduction of 50% or more days per week with mushy or watery stools. These endpoints are far from complete reprieve of IBS symptoms and, we think, underscores not only the difficulty in effectively addressing the disease but also, when we look at the substantial revenue generated by and number of prescriptions written for these drugs, how desperate IBS sufferers are for something that will provide even minor and temporary relief.

Current IBS Endpoint Guidelines

Indication	Primary Endpoints	Entry Criteria	Responder Definition
IBS-C		**Abdominal Pain Intensity**	**Abdominal Pain Intensity**
	Abdominal Pain Intensity	Weekly average of *worst abdominal pain in past 24 hours* score of ≥ 3.0 on a 0 to 10 point scale	Decrease in weekly average of *worst abdominal pain in the past 24 hours* score of at least 30% compared with baseline
	AND	AND	AND
	Stool Frequency	**Stool Frequency**	**Stool Frequency**
		< 3 CSBMs per week	Increase of 1 or more CSBM per week compared with baseline
IBS-D		**Abdominal Pain Intensity**	**Abdominal Pain Intensity**
	Abdominal Pain Intensity	Weekly average of *worst abdominal pain in past 24 hours* score of ≥ 3.0 on a 0 to 10 point scale	Weekly responder defined as: decrease in weekly average of *worst abdominal pain in past 24 hours* score of at least 30% compared with baseline
	AND	AND	Daily responder defined as: decrease in *worst abdominal pain in the past 24 hours* score of at least 30% compared with baseline
	Stool Consistency	**Stool Consistency**	AND
		At least 2 days per week with at least one stool that has a consistency of Type 6 or Type 7 BSS (see Figure 1 for details)	**Stool Consistency**
			Weekly responder defined as: decrease at least 50% in the number of days per week with at least one stool that has a consistency of Type 6 or 7 compared with baseline
			Daily responder defined as: a patient whose stool consistency is less than 5 for all bowel movements on that day or no bowel movement

SOURCE: US Dept HHS, FDA, CDER. IBS– Clinical Eval of Drugs. May 2012

Unmet Need For Relief Drives Demand For Drugs, Despite Being Barely Better Than Placebo…
IBS sufferers' high unmet need for any symptom relief becomes even more obvious when examining primary endpoint outcomes data from the pivotal FDA studies of each of the four prescription drugs that account for 90%+ of the U.S. IBS drug market. In the table below we have summarized efficacy data of the phase III studies used to support FDA approval filings for each of the leading IBS drugs (see Appendix for more details about each compound and the phase III studies). Also included is Trulance, for which an FDA filing for IBS-C is expected to happen in the near term.

Our table also includes estimated current annualized U.S. sales and total prescriptions as well as our comments, all meant to help elucidate the significant demand for IBS drugs despite their relative lack of effectiveness and in many cases, highly unpleasant and even dangerous side effects.

Points of particular interest:

- **Majority of patients did not respond**: response rates ranged from a low of approximately 12% up to 41%
- **Barely more effective than placebo**: response rates as compared to placebo indicate a substantial placebo effect in treatment "response". While subjectivity of endpoint measures (particularly with 'legacy' measures) may play a part (our supposition), the data suggests that none of these drugs are much more effective than placebo. As an example, Linzess, which currently generates ~$600M in annual U.S. revenue and for which ~2.8M prescriptions are written each year, demonstrated only 7% - 13% superiority on primary efficacy endpoints compared to placebo
- **Drawbacks**: besides cost and relatively low efficacy there are other drawbacks to IBS drugs. This includes side effects which are often unpleasant - such as diarrhea, and which can even be dangerous – Lotronex carries a black box warning related to the risk of potentially serious GI events. Some drugs, such as Xifaxan, are not recommended for chronic use while others, such as Amitiza and Lotronex, are only indicated for women due to lack of data for use with men

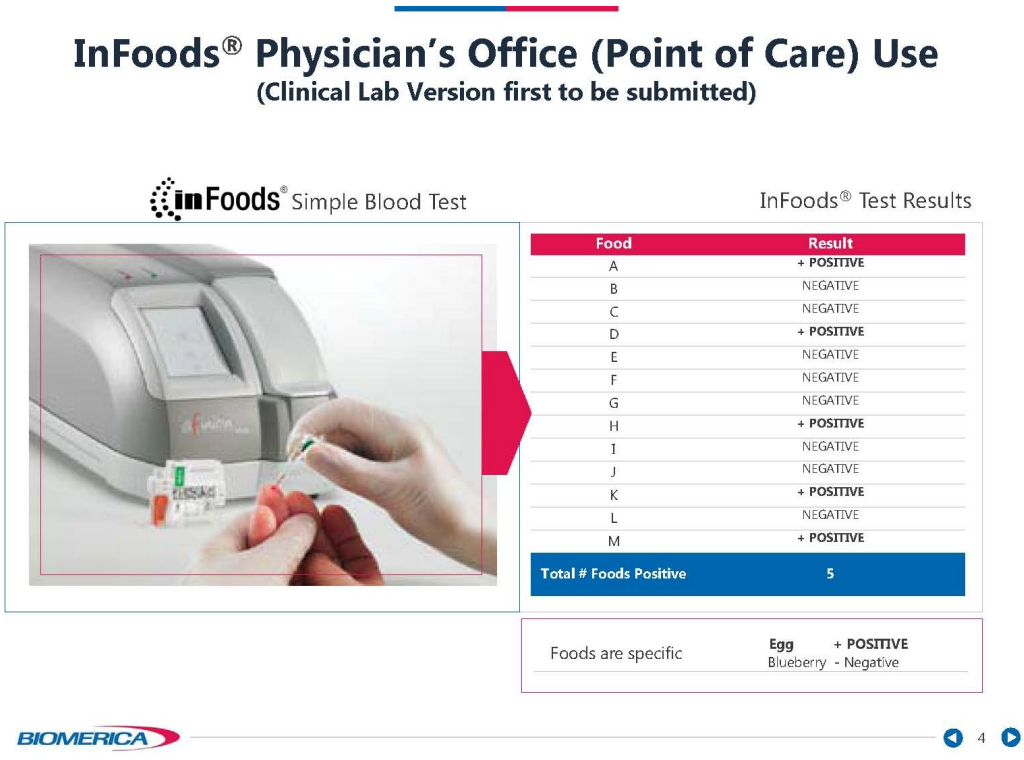
Indication	Drug	FDA Appr	Treatment Response	Delta vs placebo	Cost*	Annualized U.S Sales (M)	TRx (M)	Comments
IBS-C	Linzess	2012	12% - 34%	7% - 13%	$382	$603**	2.80**	Diarrhea side effect (20%)
	Amitiza	2008	13%	6%	$380	$409**	1.56**	Indicated for w omen only as not studied for men
	Trulance	NA	22% - 30%	7% - 12%	NA	NA	NA	Not yet FDA approved
IBS-D	Xifaxan	2015	41%	9%	$550	$950***	1.00***	Not for chronic use
	Viberzi	2015	25% - 30%	7% - 14%	$1,000	$125	0.15	Abdominal pain (secondary) endpoint not met
	Lotronex	2002	NA	13% - 20%	$940	$60	0.04	For w omen only. Black box w arning

*Cost - per Drugs.com. Based on retail price of 30-day supply of lowest dose **Includes CIC and IBS-C
***Includes overt HE and IBS-D

The Low "Attractiveness Hurdle" Should Play In InFoods' Favor…
While there is not yet enough publicly available information relative to the performance of InFoods to make any informed opinions regarding its clinical effectiveness, the current lack of effective therapies and debilitating symptoms of the disease means that doctors and patients are likely to be receptive to just about anything that has the potential to provide even incremental benefit (whether it be incremental to existing therapies or alone).

We believe that the minimal effectiveness and drawbacks of prescription drugs means that the "attractiveness hurdle" that novel IBS therapies must meet to generate interest from the ~$1B+ U.S. IBS market is relatively low. That should be particularly true for non-drug, side-effect-free products such as InFoods.

And with InFoods testing expected to be covered with existing CPT codes, coupled with the likelihood of a substantial cost-benefit as compared to IBS drugs, we think the market could be very receptive to the product. We look forward to updates from the company on expected clinical trial design and other details related to validating effectiveness and clinical utility of the test.



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, Linzess, Amitiza, Viberzi and Lotronex (see our discussion below) only treat the symptoms but not the underlying cause, are effective in only about 15% - 20% of IBS sufferers, often provide only temporary and partial relief (in those patients who do show a response) and can have unwelcome side effects
    - While new IBS drugs are in development, including at least one (Trulance) that could gain FDA approval and launch in the coming months, these also only address IBS symptoms and not the underlying cause
    - FDA has a low effectiveness hurdle related to approving IBS drugs – which also speaks to the lack of effective treatments for the disease
    - 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

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 recently 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 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%), not being useful in the diagnosis of IBS-C 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.

And particularly telling of the desperation and difficulty in developing effective IBS therapies is the low FDA efficacy hurdle used to evaluate IBS drugs and the less than compelling clinical trial data used to (successfully) support FDA approval. Minimal effectiveness and drawbacks of IBS drugs has created what we believe is a relatively low "attractiveness hurdle" and, coupled with a lack of side effects and expected cost-benefit, one that may be easily cleared if InFoods is able to demonstrate only incremental benefit (either alone or to existing therapies).

Value BMRA at $4.00/share

We use sum of the parts to value BMRA; the base business (everything except InFoods) plus InFoods. We note that we do not yet model the novel h. pylori test that recently commenced clinical studies. 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, BMRA's base business is valued at approximately $2.60/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	-1.2	15.5	N/A	1.0	19.8	1.2	1.2
OXFD	N/A	N/A	N/A	7.0	N/A	4.2	3.9
CEMI	N/A	N/A	0.0	5.2	N/A	4.3	3.6
VIVO	30.5	22.4	13.4	3.8	12.2	3.3	3.2
QDEL	N/A	N/A	N/A	6.6	35.0	6.6	6.2
ABAX	33.0	34.4	27.9	3.9	17.5	4.7	4.4
Average	**31.8**	**24.1**	**20.6**	**4.6**	**21.1**	**4.0**	**3.7**

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	N/A	N/A	-$0.20	$2.61	$2.43	$2.72	**$2.59**

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 $2.60/share for the base business and $1.50/share for InFoods values the entire company at approximately **$4.00/share.**

APPENDIX: IBS Drugs Overview

Xifaxan (Salix/Valeant):

- Xifaxan (rifaximin) is a semisynthetic antibiotic initially approved by FDA (May 2004) for the treatment of traveler's diarrhea caused by E. coli (200mg), in March 2010 it (550mg) received FDA approval for overt hepatic encephalopathy and in May 2015 it (550mg) received FDA approval for the treatment of IBS-D in adults.
- Recommended dosing is one tablet, 3x/per day for 14 days. Recurrence can be retreated twice at the same dosing regimen
- Method of action is not completely understood, but hypothesized to relate to changes in the bacterial content in the GI tract
- Most commonly reported side effects are nausea (~3%) and increase in ALT (liver enzyme in the blood, 2%)
- Clinical data used to support FDA filing consisted of three double-blind, placebo-controlled phase 3 trials (TARGET 1,2,3).
    - **Trials 1 and 2**: enrolled 1,258 patients diagnosed (per Rome II criteria) with IBS symptoms of abdominal pain and discomfort. Patients were randomized to Xifaxan (n=624) or placebo (n=634) for 14 days and followed for a subsequent 10-week treatment-free period.
    - **Primary endpoint** was proportion of patients who achieved adequate relief (based on patients' 'yes' or 'no' response) of IBS symptoms for at least 2 of 4 weeks during the month following 14 days of treatment. Key **secondary endpoint** was proportion of patients who achieved relief of bloating during the same primary evaluation period.
    - **Results:**
        - **Primary endpoint** of the combined studies: Significantly (p<0.001) more Xifaxan patients (41%) than placebo patients (32%) reported adequate relief of IBS symptoms. Relief from IBS symptoms maintained statistically significant through the entire 3-month study period (p<0.001).
        - **Results on the key secondary endpoint** were similar to that of the primary endpoint with significantly (p<0.001) more Xifaxan patients (40%) than placebo patients (30%) reporting adequate relief of IBS-related bloating.
    - **Trial 3** was powered to assess effectiveness of Xifaxan in cases of recurrence. 636 patients who did not meet a composite endpoint in TARGET 1,2 of relief of abdominal pain and loose stools were randomized in TARGET 3 for retreatment and received Xifaxan (n=328) or placebo (n=308) for another 14 days, followed by a 4 week treatment-free period. **Results** showed that significantly (p=0.02) more Xifaxan (33%) patients achieved symptom relief as compared to placebo patients (25%)

	Proportion of Patients with Response					
Primary endpoint	**Xifaxan**	**%**	**Placebo**	**%**	**Difference**	**P-value**
Weekly global IBS symptoms						
Target 1	126/309	40.8%	98/314	31.2%	9.6%	0.01
Target 2	128/315	40.6%	103/320	32.2%	8.4%	0.03
Combined	254/624	40.7%	201/634	31.7%	9.0%	< 0.001
Key secondary endpoint	**Xifaxan**	**%**	**Placebo**	**%**	**Difference**	**P-value**
Weekly IBS-related bloating						
Target 1	122/309	39.5%	90/314	28.7%	10.8%	0.005
Target 2	129/315	41.0%	102/320	31.9%	9.1%	0.02
Combined	251/624	40.2%	192/634	30.3%	9.9%	< 0.001

Viberzi (Allergan):

- Viberzi (eluxadoline) received FDA approval May 2015 for the treatment of IBS-D in adults. Launched in U.S. December 2015
- Eluxadoline targets opioid receptors (it is a μ- and κ-opioid receptor agonist and δ-opioid receptor antagonist) in the portion of the nervous system that govern the GI tract, thereby reducing bowel contractions and related pain.
- Recommended dosing is one tablet, 2x/day and can be taken as long as doctor recommends
- Most commonly reported side effects are constipation, nausea and abdominal pain
- Clinical data used to support FDA filing consisted of two Phase 3 double-blind, placebo controlled studies
    - Combined studies enrolled 2,425 patients (study 1 = 1,280, study 2 = 1,145) diagnosed with IBS-D (Rome III criteria) randomized to either 75mg or 100mg Viberzi (n=1,616) twice daily or placebo (n=809)
    - Patients treated over 26 weeks
    - Primary endpoint was simultaneous improvement in worst abdominal pain score by $\geq$ 30% as compared to baseline and improvement in stool consistency (based on Bristol Stool Scale) on at least 50% of the days within a 12-week time interval (for FDA) and through 26 weeks (for EMA)
    - Secondary endpoints included improvement in the defined pain score at 12 weeks and improvement in the defined stool consistency score at 12 weeks
    - **Results**:
        - 12 weeks on composite (primary FDA) endpoint (pain and stool):
            - Study 1: 24% (75mg) to 25% (100mg) of Viberzi patients vs. 17% of placebo patients met composite endpoint, indicating statistically significant improvement favoring treatment arm of 7% - 8% ($p < 0.05$)
            - Study 2: 29% to 30% of Viberzi patients vs. 16% of placebo patients met composite endpoint, indicating statistically significant improvement favoring treatment arm of 13% - 14% ($p < 0.001$)
        - 26 weeks on composite (primary EMA) endpoint (pain and stool):
            - Study 1: 23% to 29% of Viberzi patients vs. 19% of placebo patients met composite endpoint. The 10% difference to the 100mg arm was statistically significant ($p \leq 0.014$) while the 4% difference to the 75mg arm was not
            - Study 2: 30% to 33% of Viberzi patients vs. 20% of placebo patients met composite endpoint. The 13% - 14% difference was statistically significant ($p \leq 0.014$)
        - 12 weeks on abdominal pain (secondary) endpoint:
            - Study 1: 42% to 43% of Viberzi patients vs. 40% of placebo patients reported reduction in abdominal pain. The 2% - 3% difference was not statistically significant
            - Study 2: 48% to 51% of Viberzi patients vs. 45% of placebo patients reported reduction in abdominal pain. The 3% - 6% difference was not statistically significant
        - 12 weeks on stool consistency (secondary) endpoint:
            - Study 1: 30% to 34% of Viberzi patients vs. 22% of placebo patients reported improvement in stool consistency. The 8% - 12% difference was statistically significant
            - Study 2: 36% to 37% of Viberzi patients vs. 21% of placebo patients reported improvement in stool consistency. The 15% - 16% difference was statistically significant

- **Rescue loperamide: % of patients requiring rescue loperamide during 26-week treatment phase**
  - Study 1: 25% of Viberzi vs. 28% of placebo
  - Study 2: 29% of Viberzi vs. 35% of placebo

	Study 1			Study 2		
	VIBERZI 100mg twice daily n=426	VIBERZI 75mg twice daily n=427	PBO n=427	VIBERZI 100mg twice daily n=382	VIBERZI 75mg twice daily n=381	PBO n=382
Composite[1] Response over 12 weeks						
Responder rates	25%	24%	17%	30%	29%	16%
Treatment difference	8%[2]	7%[4]		13%[3]	13%[3]	
95% CI (%)	(2.6, 13.5)	(1.4, 12.2)		(7.5, 19.2)	(6.8, 18.5)	
Composite Response over 26 weeks						
Responder rates	29%	23%	19%	33%	30%	20%
Treatment difference	10%	4%		13%	10%	
95% CI (%)	(4.7, 16.1)	(-1.0, 9.9)		(6.4, 18.8)	(4.2, 16.4)	
Abdominal Pain Response Improved ≥30% over 12 weeks						
Responder rates	43%	42%	40%	51%	48%	45%
Treatment difference	4%	3%		6%	3%	
95% CI (%)	(-3.0, 10.2)	(-3.8, 9.4)		(-1.3, 12.8)	(-4.3, 9.8)	
BSS <5 Response over 12 weeks						
Responder rates	34%	30%	22%	36%	37%	21%
Treatment difference	12%	8%		15%	16%	
95% CI (%)	(6.3, 18.2)	(2.1, 13.8)		(8.4, 21.0)	(9.7, 22.4)	

[1]Composite= Simultaneous improvement of Worst Abdominal Pain (WAP) by ≥30% and Bristol Stool Score (BSS) < 5 on the same day for ≥ 50% of days over the interval
[2] $P<0.01$
[3] $P<0.001$
[4] $P<0.05$

SOURCE: Viberzi label, Actavis. Accessdata.fda.gov

Linzess (Allergan):

- Linzess (linaclotide) is a peptide agonist of guanylate cyclase 2C (GC-C) approved by FDA in 2012 for the treatment of adults with IBS-C as well as for the treatment of chronic idiopathic constipation (CIC)
- Recommended dosing is one tablet daily
- Most commonly reported side effects are diarrhea (20%), abdominal pain (7%) and flatulence
- Method of action: linaclotide stimulates secretion of intestinal fluid resulting in acceleration of GI transit and reduction on abdominal pain
- Clinical data used to support FDA approval for IVS-C consisted of two double-blind, randomized, placebo-controlled phase 3 studies
  - Combined studies enrolled 1,604 patients (study 1 = 800, study 2 = 804) diagnosed with IBS-C (Rome II criteria) randomized to either Linzess (n=806) or placebo (n=798)
  - Patients treated for 12 weeks
  - Primary endpoint: there were four primary endpoints:
    - In at least 9 of the first 12 weeks of treatment patient had to have;
      - Combined responder endpoint (9 of 12 weeks): ≥ 30% reduction from baseline in abdominal pain, ≥ 3 complete spontaneous bowel movements (CSBM) and an increase of ≥ 1 CSBM from baseline, all in the same week
      - ≥ 30% reduction from baseline in abdominal pain

- ≥ 3 complete spontaneous bowel movements (CSBM) and an increase of ≥ 1 CSBM from baseline in the same week

- Combined responder endpoint (6 of 12 weeks): In at least 6 of the first 12 weeks of treatment patient had to have ≥ 30% reduction from baseline in abdominal pain and an increase of ≥ 1 CSBM from baseline, all in the same week

- **Results:**
  - Combined responder 9 of 12 weeks:
    - Study 1: 12% of Linzess vs. 5% of placebo met endpoint
    - Study 2: 13% of Linzess vs. 3% of placebo met endpoint
  - Abdominal pain 9 of 12 weeks:
    - Study 1: 34% of Linzess vs. 27% of placebo met endpoint
    - Study 2: 39% of Linzess vs. 20% of placebo met endpoint
  - CSBM 9 of 12 weeks:
    - Study 1: 20% of Linzess vs. 6% of placebo met endpoint
    - Study 2: 18% of Linzess vs. 5% of placebo met endpoint
  - Combined responder 6 of 12 weeks:
    - Study 1: 34% of Linzess vs. 21% of placebo met endpoint
    - Study 2: 34% of Linzess vs. 14% of placebo met endpoint
  - Differences between treatment and placebo arms on all endpoints were statistically significant

At least 9 of first 12 weeks

	Trial 1			Trial 2		
	LINZESS 290 mcg (N=405)	Placebo (N=395)	Treatment Difference [95% CI]	LINZESS 290 mcg (N=401)	Placebo (N=403)	Treatment Difference [95% CI]
Combined Responder* (Abdominal Pain and CSBM Responder)	12.1%	5.1%	7.0% [3.2%, 10.9%]	12.7%	3.0%	9.7% [6.1%, 13.4%]
Abdominal Pain Responder* (≥ 30% Abdominal Pain Reduction)	34.3%	27.1%	7.2% [0.9%, 13.6%]	38.9%	19.6%	19.3% [13.2%, 25.4%]
CSBM Responder* (≥ 3 CSBMs and Increase ≥1 CSBM from Baseline)	19.5%	6.3%	13.2% [8.6%, 17.7%]	18.0%	5.0%	13.0% [8.7%, 17.3%]

At least 6 of first 12 weeks

	Trial 1			Trial 2		
	LINZESS 290 mcg (N=405)	Placebo (N=395)	Treatment Difference [95% CI]	LINZESS 290 mcg (N=401)	Placebo (N=403)	Treatment Difference [95% CI]
Combined Responder* (Abdominal Pain and CSBM Responder)	33.6%	21.0%	12.6% [6.5%, 18.7%]	33.7%	13.9%	19.8% [14.0%, 25.5%]

* Primary Endpoint, ** Secondary Endpoints
Note: Analyses based on first 12 weeks of treatment for both Trials 1 and 2
CI =Confidence Interval

SOURCE: Linzess label. Allergan

Amitiza (Takeda):

- Amitiza (lubiprostone) received initial FDA approval in 2006 for the treatment of chronic idiopathic constipation in adults and in 2008 received FDA approval for the treatment of women with IBS-C
- Amitiza is a bicyclic fatty acid that acts on GI epithelial cells to promote secretions which helps to soften the stool and increase motility
- Recommended dosing for IBS-C is orally, twice daily
- Most common side effects are nausea (8%), diarrhea (7%) and abdominal pain (5%)

- Clinical data used to support FDA approval for IBS-C consisted of two double-blind, placebo-controlled phase 3 studies (Note: FDA guidelines for evaluating novel IBS drugs changed in 2012; i.e. after Amitiza rec'd FDA approval)
    - Combined studies enrolled 1,154 patients (92% of which were female) with IBS-C and received Amitiza 2x/day or placebo for 12 weeks
    - Primary endpoint compared the proportion of "Overall responders" in each arm based on 7-point global relief questionnaire. "Monthly responder" was defined as reporting "significantly relieved" for at least 2 weeks of the month or at least "moderately relieved" in all four weeks of the month. "Overall responders" were those that were "monthly responders" for at least 2 of the 3 months of the study.
    - Results:
        - Study 1: 14% of Amitiza patients vs. 8% of placebo patients were "overall responders"
        - Study 2: 12% of Amitiza patients vs. 6% of placebo patients were "overall responders"
        - In both studies the difference between treatment and placebo was statistically significant

Lotronex (Prometheus):

- Lotronex (Alosetron) originally received FDA approval in February 2002 for the treatment of women with IBS-D but the manufacturer voluntarily removed it from the market later that year due to reports that use of it had been associated with life-threatening adverse effects including serious intestinal damage and severely obstructed bowels. In 2002 FDA approved an sNDA, allowing for restricted marketing of Lotronex only for women with severe diarrhea-predominant IBS. Less than 5% of IBS is considered severe. The revised labeling also includes a black box warning related to potentially serious GI adverse events
- Lotronex acts as an agonist to receptors of the GI-related nervous system, helping to increase water absorption and slow GI motility
- Recommended dosing is orally, twice per day for 12 weeks
- Most commonly reported side effects are constipation (29%), abdominal pain (7%) and nausea (6%)
- Clinical data: Lotronex has been studied in three clinical studies in women with severe diarrhea-predominant IBS, including two studies (i.e. studies 1,2) with patients with bowel urgency $\geq$ 50% of days and one study (i.e. study 3) with patients with 1 or more of the following: frequent and severe abdominal pain or discomfort, frequent bowel urgency or fecal incontinence, disability or restriction of daily activities due to IBS
    - **Results**;
        - Studies 1,2: Lotronex patients had 13% to 16% (statistically significant) greater increase compared to placebo patients in the median percentage of days with bowel urgency control. In addition, 50% of Lotronex patients had bowel urgency no more than 1 day in the last week compared to 29% of placebo patients. Also, 12% of Lotronex patients had bowel urgency no more than 2 days per week in any of the 12 treatment weeks compared to 1% of placebo patients
        - Study 3: Lotronex dosed at three different doses; 0.5mg/day, 1mg/day or 1mg 2x/day. All Lotronex groups had significantly greater number of responders (43% to 51%) versus placebo (31%) based on 7point GIS scale at 12 weeks

IN LATE-STAGE DEVELOPMENT

Trulance (Synergy):

- Trulance (plecanatide) received FDA approval for the treatment of adults with chronic idiopathic constipation in January 2017. It has also completed two phase 3 trials for the treatment of IBS-C, an indication for which Synergy has said they expect to file an sNDA for in Q1 2017.

- Similar to Linzess, Trulance is a GC-C agonist. It is a 16 amino acid peptide which acts to stimulate increased intestinal fluid and accelerate GI transit.
- Recommended dosing for IBS-C is orally once/day
- Clinical studies: Top-line data from two (3mg and 6mg doses) phase 3 studies in IBS-C was released in December 2016.
    - Combined studies enrolled 2,189 patients (study 1 = 1,135, study 2 = 1,054) with IBS-C who were randomized to Trulance (n = 1,456) or placebo (n = 733)
    - Patients treated once daily for 12 weeks
    - Primary endpoint is percentage of patients who are "overall responders", defined as those patients that simultaneously experience $\geq$ 30% reduction in worst abdominal pain and increase of $\geq$ 1 CSBM from baseline, in the same week, for at least 50% of the 12 treatment weeks
    - **Top-line results**
        - Study 1 (n = 1,135): 21.5% of Trulance 3mg and 24.0% of Trulance 6mg patients vs. 14.2% of placebo patients met primary endpoint. The difference between placebo and both Trulance dose cohorts was statistically significant (p=0.009 for 3mg, p<0.001 for 6mg)
        - Study 2 (n = 1,054): 30.2% of Trulance 3mg and 29.5% of Trulance 6mg patients vs. 17.8% of placebo patients met primary endpoint. The difference between placebo and both Trulance dose cohorts was statistically significant (p<0.001) for 3mg, p<0.001 for 6mg)
        - Adverse events: the most common adverse event in the IBS-C phase 3 studies have been diarrhea (~4%)

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.

	2017 A	Q1A	Q2E	Q3E	Q4E	2018 E	2019 E	2020 E	2021 E
Total Revenues	$5,791.7	$1,444.5	$1,510.1	$1,623.9	$1,599.4	$6,177.8	$6,696.8	$7,173.1	$7,680.0
YOY Growth	*12.7%*	*2.4%*	*5.4%*	*8.3%*	*10.3%*	*6.7%*	*8.4%*	*7.1%*	*7.1%*
Cost of Goods Sold	$3,769.9	$929.9	$966.4	$1,042.6	$1,007.6	$3,946.5	$4,085.0	$4,339.7	$4,608.0
Gross Income	$2,021.9	$514.6	$543.6	$581.4	$591.8	$2,231.3	$2,611.7	$2,833.4	$3,072.0
Gross Margin	*34.9%*	*35.6%*	*36.0%*	*35.8%*	*37.0%*	*36.1%*	*39.0%*	*39.5%*	*40.0%*
SG&A	$1,845.8	$452.0	$468.1	$518.0	$476.6	$1,914.8	$2,022.4	$2,087.4	$2,204.2
% SG&A	*31.9%*	*31.3%*	*31.0%*	*31.9%*	*29.8%*	*31.0%*	*30.2%*	*29.1%*	*28.7%*
R&D	$1,130.7	$288.6	$335.0	$368.0	$401.0	$1,392.6	$1,385.0	$867.0	$841.0
% R&D	*19.5%*	*20.0%*	*22.2%*	*22.7%*	*25.1%*	*22.5%*	*20.7%*	*12.1%*	*11.0%*
Operating Income	($954.6)	($226.0)	($259.5)	($304.7)	($285.8)	($1,076.0)	($795.7)	($121.0)	$26.8
Operating Margin	*-16.5%*	*-15.6%*	*-17.2%*	*-18.8%*	*-17.9%*	*-17.4%*	*-11.9%*	*-1.7%*	*0.3%*
Total Other Income (Expense)	$46.1	$19.0	$11.2	$8.4	$3.4	$42.0	$28.0	$30.0	$25.0
Pre-Tax Income	($908.5)	($207.1)	($248.3)	($296.3)	($282.4)	($1,034.1)	($767.7)	($91.0)	$51.8
Tax expense (benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Net Income	($908.5)	($207.1)	($248.3)	($296.3)	($282.4)	($1,034.1)	($767.7)	($91.0)	$51.8
YOY Growth	*-39.4%*	*74.7%*	*14.9%*	*-2.3%*	*-7.0%*	*13.8%*	*-25.8%*	*-88.1%*	*-157.0%*
Net Margin	*-15.7%*	*-14.3%*	*-16.4%*	*-18.2%*	*-17.7%*	*-16.7%*	*-11.5%*	*-1.3%*	*0.7%*
EPS	($0.11)	($0.02)	($0.03)	($0.03)	($0.03)	($0.12)	($0.08)	($0.01)	$0.01
YOY Growth	*-44.5%*	*70.8%*	*12.2%*	*-3.6%*	*-7.2%*	*10.8%*	*-30.6%*	*-88.4%*	*-155.8%*
Diluted Shares O/S	8,330	8,511	8,515	8,560	8,635	8,555	9,150	9,325	9,525

Brian Marckx, CFA

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