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Zacks Small-Cap Research

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Biomerica Inc (BMRA-NASDAQ)

BMRA: Encouraged By Robustness (with first glimpse) of InFoods' Study Design

We use sum of the parts to value BMRA. Comparable P/S and P/B values the base business at ~$3.00/share. Applying 11x to our $8.4M 2024 forecasted InFoods revenue and discounting back to the present at 15%/year, results in InFoods present value of approximately $35M, or $4.00/share. BMRA TOTAL VALUE = $7/share

Current Price (04/18/18)	$4.00
Valuation	**$7.00**

OUTLOOK

Q3 revenue, down 8% yoy and 15% qoq, was softer than we were expecting with both Europe and U.S. sales contributing to the miss. While Asia sales dipped sequentially, they came in a few hairs better than we had forecast and turned in the seventh consecutive quarter of yoy growth. The 40% yoy revenue growth from Asia, which remains BMRA's most significant territory and accounts for almost 50% of total revenue, offset some of the relative softness in the U.S. and Europe and helped limit total revenue contraction to the high single digits. We continue to think the recent sales momentum, coupled with contribution from EZ Detect (which received CFDA approval in January 2018), bode well for continued double-digit annual growth in Asia sales over the next couple of years.

InFoods Study 1 was first posted on clinicaltrials.gov on March 9, 2018 and provides a little more insight (than we had had previously) to the expected design of both the initial and pivotal studies. Study 1 is of robust design, RCT and triple blinding. Clearly Study 1 was designed to serve as a template for a pivotal study. Inclusion and exclusion criteria all appear to be consistent with designs of pivotal IBS drug studies – which is also highly encouraging.

SUMMARY DATA

52-Week High	**$9.32**
52-Week Low	**$2.25**
One-Year Return (%)	**80.09**
Beta	**-0.63**
Average Daily Volume (sh)	**35,650**
Shares Outstanding (mil)	**9**
Market Capitalization ($mil)	**$34**
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 (%)	**0.1**
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	1.61 A	1.38 A	1.53 E	5.96 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 A	-$0.04 A	-$0.06 E	-$0.15 E
2019					-$0.41 E
2020					-$0.31 E

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

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WHAT'S NEW……

Q3 2018 Results: *Asia Remains Strong While U.S., Europe Slip. InFoods Study 1 Design Posted on clinicaltrials.gov...*

Biomerica reported financial results for their fiscal 2018 third quarter ending February 28, 2018. Revenue, down 8% yoy and 15% qoq, was softer than we were expecting with both Europe and U.S. sales contributing to the miss.

- Fiscal Q3 has historically been a relatively strong quarter for BMRA's U.S. business – and while that proved to be true as compared to the first two quarters of 2018, on a prior years' basis, domestic sales were relatively very weak – in fact, the lowest Q3 U.S. number since at least 2009. We remain optimistic, however, that U.S. activity will come back and believe a possible catalyst to U.S. sales growth could come from the new h. pylori test candidate which just enter clinical studies
- Europe, while down both yoy and sequentially in Q3, has held much better than the U.S. And, to be fair, the prior year comp was a (somewhat anomalistically high) tough one to beat. But, unfortunately, European revenue YTD is now running (slightly) below the prior year and unless we see a marked qoq rebound in Q4, Europe, which accounts for a relatively hefty 35% of total revenue, could put a damper on BMRA's full-year 2018 revenue growth. Nonetheless, we do not think Europe will contract by more than single-digits in 2018.
- While Asia sales dipped sequentially, they came in a few hairs better than we had forecast and turned in the seventh consecutive quarter of yoy growth. The 40% yoy revenue growth from Asia, which remains BMRA's most significant territory and accounts for almost 50% of total revenue, offset some of the relative softness in the U.S. and Europe and helped limit total revenue contraction to the high single digits. We continue to think the recent sales momentum, coupled with contribution from EZ Detect (which received CFDA approval in January 2018), bode well for continued double-digit annual growth in Asia sales over the next couple of years. EZ Detect also recently (i.e. March 2018) received regulatory approval in Mexico where it should also begin to make a material revenue contribution during fiscal 2018.

While total revenue was not a highlight in Q3, gross margin held up well and operating expenses remained on the moderate side – both of which helped keep operating loss less in-the-red than we had anticipated. We do, however, continue to model opex to increase at a higher rate than that of revenue growth through at least the end of fiscal 2019 (ending May 2019) as a result of InFoods U.S. clinical trial related expenses.

Revenue

Q3 revenue of $1.38M was down 8% yoy (from $1.50M in Q3 '17), down 15% sequentially (from $1.61M in Q2 '18) and about 11% below our $1.54M estimate.

U.S. revenue, at $208k was down 40% yoy but up 51% from Q2 of this year. U.S. sales have trended relatively soft since 2015 when they fell 17% to $1.0M in that year. They dipped another 4% in 2016 and shed 12% the next year, ending 2017 at just $874k. The run-rate through the first nine months of the current year puts U.S. sales on-track to end 2018 at around $630k – an implied 28% yoy contraction and the lowest level since at least 2010 (i.e. the furthest back that we looked).

We, however, model U.S. sales to stabilize at or around recent levels (related to the company's current product portfolio) over the near-term. A possible catalyst to U.S. sales growth could come from a new h. pylori test, clinical trials for which just recently commenced enrollment (and which we discuss in more detail below).

And with the recent disclosure and announcement of initial clinical trial design and collaboration to conduct clinical trials with two major U.S. university research centers, we recently began modeling InFoods. As we discuss in more detail below, we are now modeling initial contribution from InFoods in 2022. We continue to believe that eventual FDA clearance of this novel IBS product would result in a significant increase in Biomerica's U.S. sales and provide the majority of total revenue from that point into the foreseeable future.

Meanwhile, **Q3 revenue from Asia** was $636k – up 40% yoy, although down 28% from Q2. We note, however, that Q2 was a tough comp given that Asia sales in that quarter were the highest they have been since Q2 2013. Q3 Asia sales were also about 6% better than we had estimated.

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. 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.

For historical context, 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. Asia sales grew another 22% through the first nine months of 2018. And among the territories which did post positive revenue growth through the first nine months of fiscal 2018, Asia contributed 86% of the total. Given the outsized contribution from Asia (which now accounts for 48% of total revenue) even incremental growth from current levels in this territory will have a meaningfully positive effect.

The continued strength in Asia sales is highly encouraging given the outsized contribution that this territory provides to total revenue. And we think sales from Asia will almost certainly grow from here given recent China Food and Drug Administration Approval (CFDA) of EZ Detect, an over-the-counter fecal occult blood (FOB) test for colorectal cancer. While Biomerica has never publicly disclosed product-specific sales numbers, we believe EZ Detect is one of the (if not the #1) best-selling products for the company. We also think Asia could be particularly receptive to the product given certain cultural principles in many parts of Asia related to hygiene which may discourage use of FOB tests which require fecal handling.

Relative to Europe - sales from this territory were a bright spot in 2017, although not nearly as robust or significant as that from 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. And while European sales eked out 5% growth through the first six months of 2018, they slid 26% yoy in Q3, resulting in YTD sales now in the red by about 7%.

Europe accounts for about 35% 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 have been encouraged by recent trends (despite the relative softness in Q3) 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 next few years.

And while we are now modeling forecasted InFoods contribution in the U.S., we still do not model any assumed commercialization of the product candidate in any other parts of the world. That could change depending on BMRA's future strategic objectives as well as if we feel there is enough information to make (comfortably) informed projections about certain commercializability-related gating factors. At this point we have no information or insight into if or when BMRA might consider targeting markets outside of the U.S. or if they do, which areas of the world they would focus on next. Europe, however, would be our best-guess as a potential front-runner if management does eventually look to expand OUS with InFoods given not only the economic similarities of most of the highly developed European countries with that of the U.S. but, perhaps more importantly, diets that are (generally) similar to that of most Americans.

Gross Margin, Operating Expenses

Gross margin, at just 33.8%, was about 200bps lower than we had forecast, although not significantly different from recent history (GM averaged 33.5% in 1H '18). But GM has slid since 2017 – through the first nine months of 2017 GM averaged 36.6% vs. 33.5% YTD 2018. More encouraging however, is that GM improved from 31.4% in Q2 '18.

Q3 OpEx was $788k, or 57% of revenue, compared to our $951k and 61% estimates. SG&A has remained flat through the first nine months of 2018 as compared to the same period in 2017 despite expanded activity in both operational and product development areas. We do, however, continue to model opex to increase at a higher rate than that of revenue growth through at least fiscal 2019 (ending May 2019) as a result of InFoods U.S. clinical trial related expenses.

Cash

BMRA raised $290k, net, during Q3 from the combination of common share sales via their ATM program and the exercise of stock options (another $160k, net, was raised via the ATM subsequent to Q3 quarter-end). Cash balance at the close of Q3 was $597, down from $818k at the end of fiscal Q2. Cash used in operating activities in the three and nine months ending February 28, 2018 was $489k and $852k ($274k and $631k, ex-changes in working capital), respectively. Another $21k and $74k was used in investing activities in the same periods.

In June 2017 Biomerica filed an S-3 registration statement with the SEC (which became effective July 20th), registering for sale (up to) $45M in common stock. Then on December 1st the company entered into an ATM agreement with B. Riley FBR, authorizing the sale of up to $7M of common shares. To-date, we calculate that approximately 97k shares have been sold under the shelf, representing net proceeds of ~$450k. As we noted

following filing of the registration statement, 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 Telcon Pharmaceuticals (fka 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". The agreement was initially cancellable if BMRA had not obtained FDA clearance/approval of InFoods by December 31, 2017 but that deadline was subsequently extended until December 31, 2019.

Operational Update (see Appendix for background info)

InFoods Clinical Trial Initial Game-plan, Clinical Site Partners Announced, Study 1 Design on clinicaltrials.gov
The most significant news since Biomerica first announced intentions to pursue a potentially game-changing 'therapy' for IBS and building what we believe is an all-star IBS-related scientific advisory board came in early January when the company disclosed the initial InFoods clinical validation strategy as well as that two leading U.S. university research centers would lead the studies.

Per their January 8, 2018 press release, two clinical studies are expected to be conducted; the purpose of the first study, which will include approximately 180 subjects and with an expected duration of 9 – 14 months, is to identify the primary endpoint to be used in the second study.

Study 1, titled simply (as of now, anyway) "Endpoint Determination Study Protocol" was first posted on clinicaltrials.gov on March 9, 2018 (NCT03459482, link: http://bit.ly/2H9RTPP). The posting did provide a little more insight (than we had had previously) to the expected design of both the initial and pivotal studies.

Particular points of interest related to Study 1 as detailed in the posting include:

- RCT-design and will incorporate triple blinding (i.e. patient, provider and investigator)
- Targeting enrollment in each arm (i.e. treatment vs. sham) of 90 patients and a minimum of 30 patients in each IBS classification of: IBS-D (diarrhea), IBS-C (constipation) and IBS-M (mixed)
- Arms
    - Treatment (i.e. food elimination diet): patients will be given an elimination diet based upon foods with a positive antibody profile in the InFoods IBS test. The elimination diet will also exclude any and all foods to which the subject has a known IgE allergy and foods the subject already currently eliminates
    - Sham: patients will be given a "Sham" elimination diet. The sham diet will eliminate the same number of foods but none of the actual foods to which the patient had a positive antibody profile in the InFoods IBS test. The sham diet will also eliminate any and all foods to which the subject has a known IgE allergy and foods the subject already currently eliminates
- Inclusion criteria includes
    - Meets Rome III or Rome IV IBS diagnostic criteria
    - Respond "No" to IBS Adequate Relief (IBS-AR) in the past week at the screening visit #1
    - Score between ≥ 3 and <7.5 on the Abdominal Pain Intensity Assessment (IBS_API) based on a weekly average of worst daily (in past 24 hours) abdominal pain on a 0 to 10 point scale
    - A positive IgG antibody response for at least one food in the InFoods IBS panel
    - Patients who are on stable (> 3 months) doses of medications or treatments for their IBS (e.g., probiotics, fiber, Viberzi, Linzess, Amitiza, Alosetron, Plecanatide, anticholinergics, antidepressants, Zofran bile acid sequestrants, or anti-diarrheals) will be allowed to continue their medications as long as no change in treatment is planned for the duration of the study and no dose adjustment is made during the duration of the study
- Exclusion criteria includes
    - Patients who have used Rifaximin in the past 3 months
    - Patients engaged in another type of diet therapy i.e. FODMAP
    - Chronic pain from other conditions besides IBS

Our Comments on Study 1 Design:
Is of robust design, RCT and triple blinding. Clearly Study 1 was designed to serve as a template for a pivotal study. Inclusion and exclusion criteria all appear to be consistent with designs of pivotal IBS drug studies – which is

also highly encouraging. The only slight divergence appears to be with excluding patients with pain score ≥ 7.5. We have no concern relative to that, however, as it almost certainly relates to minimizing potential noise given that higher pain scores can often be associated with non-IBS causes.

A "primary endpoint" of IBS-API (i.e. pain measure) is also listed in the clinicaltrials.gov posting – however, that should be considered to only be one of several measures that will be assessed in Study 1 as potential primary endpoints to be incorporated into a pivotal study. Others, as we have indicated in our recent prior updates, will likely include primary endpoints that have been used in recent pivotal studies of IBS drugs including defecation related endpoints (i.e. stool consistency and frequency). We should know more about all of the endpoints under consideration when with future updates to the posting.

The clinical studies will be conducted at Beth Israel Deaconess Medical Center (Harvard teaching hospital) and the University of Michigan. Drs. William Chey and Anthony Lembo are members of BMRA's scientific advisory board and are affiliated with the University of Michigan and Beth Israel Deaconess Medical Center, respectively (and will presumably be the principal investigators at their respective trial sites). As a reminder, Dr. Lembo is Director of the GI Motility Laboratory at the Beth Israel Deaconess Medical Center's Division of Gastroenterology. He is also one of the principal investigators of Biomerica's recently initiated h. pylori clinical study (see below). Dr. 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.

Comment on Primary Endpoint…
We will be very interested to eventually find out what InFoods' pivotal study primary endpoint will be and its similarity (or not) to those used in prescription IBS drugs' pivotal studies (see our Appendix for more detail about primary endpoints).

Given that FDA has already determined InFoods is a non-significant risk diagnostic (i.e. Class I), the efficacy hurdle for U.S. regulatory clearance may be considered to already be set inherently relatively low (which is not uncommon for diagnostics of many conditions and diseases). However, FDA clearance of a diagnostic usually does not portend the commercial potential of that of a drug that also successfully gains U.S. regulatory approval. In other words, while FDA clearance is of obvious importance for InFoods to enter the U.S. market, meaningful physician uptake may require "compelling enough" clinical evidence.

The good news for BMRA is that there are several factors which may mean the "compelling enough" hurdle may not be too difficult to clear – which we discuss below. The choice of primary endpoint in InFoods' clinical studies may have significant influence (perhaps the most influence) on commercial adoption. If InFoods' primary endpoint is the same (or at least similar) to those used in IBS drug pivotal studies, that should allow for an apples-to-apples efficacy comparison between them - and the additional benefit would be that GIs are already versed on them.

But while a similar endpoint might be ideal, as long as whatever measure is chosen has been sufficiently validated (and InFoods demonstrates efficacy), we think there will be demand for InFoods. The fact that InFoods can be used as an addition to IBS drug therapy means that BMRA's diagnostic does not have to demonstrate superiority to current prescription medicine – in this scenario, as long as InFoods can provide incremental benefit to drugs, it should have utility.

"Compelling Enough" May Not Be Tough Given InFoods Appeal to the "3Ps"…
With BMRA's dream-team scientific advisory board presumably guiding InFoods' clinical strategy, we have confidence that whatever endpoint is chosen will have sufficient industry acceptance. Assuming success in the clinical studies, we like the chances for significant adoption of InFoods because of its potential to appeal to the "3Ps" in the healthcare treatment chain – that is, the patient, physician and payer. Here's why;

- **IBS Drugs Have Major Drawbacks (see our detailed discussion in Appendix):**
    - data from pivotal FDA studies of currently available Rx IBS drugs have shown that;
        - they are ineffective for the majority of IBS sufferers
        - they were often barely better than placebo
        - most IBS drugs have a negative effect on IBS that exceeds their benefits[1]
    - IBS Rx drugs are expensive
        - typical cost-per Rx between $400 - $1,000

[1] Shah, E. and Pimentel, M. (2014), Evaluating the functional net value of pharmacologic agents in treating irritable bowel syndrome. Aliment Pharmacol Ther, 39: 973–983. doi:10.1111/apt.12692

        - due to the high cost of IBS drugs and the chronic nature of the disease, payers will often require patients to try other, less-expensive, therapies before approving payment
        - lack of efficacy and high cost of drugs drives up total IBS-related healthcare costs as physicians use trial and error approach to try and treat the disease
    - IBS drugs can have unpleasant (such as diarrhea) and dangerous (such as risk of pancreatitis) side effects. Some are also not recommended for chronic use
    - there is no drug indicated for the treatment of IBS-M

- **Pent-up Demand for Better IBS Treatment of Options**
    - IBS, particularly IBS-D, can be highly detrimental to quality of life
    - given that IBS drugs do not provide sufficient relief to most IBS sufferers, physicians and patients are eager for other options
    - survey conducted by a 3rd-party research organization found that 70% of physicians surveyed indicated that they would use InFoods

- **Reimbursement**
    - BMRA (as guided by their IBS-expert SAB) believes InFoods is reimbursable under an existing CPT code(s), although they have yet to divulge which one(s)
    - we estimate (i.e. guess) that an InFoods diagnosis will charge will be in the range of $100 - $300 and a patient can expect to be tested 2 – 3 times per year = $400 - $900/year. This is relatively insignificant compared to the ~$13k/year current average total healthcare cost per IBS-D patient which may further incentivize payers to reimburse for InFoods
    - as noted above, payers often require failure of less expensive (i.e. oftentimes non-Rx and not IBS indicated) treatment options prior to authorizing payment for Rx IBS drugs. As such, InFoods may be able to be positioned as a less expensive, first-line option to IBS

Novel H. Pylori Test Clinical Studies Commence Enrollment

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 November 2017 BMRA announced that enrollment commenced for the clinical studies 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." 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.[2]

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 ($34M 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.

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

VALUATION

We like chances for FDA clearance of InFoods and subsequent commercial demand…
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).

And in terms of the potential commercial appeal for InFoods, the dearth of sufficiently effective IBS therapies, high related healthcare costs and overall frustration from physicians and patients as a result of lack of better options means high demand already exists for more effective IBS therapies. Couple that with payers' pushback to reimburse for (relatively expensive) Rx IBS drugs until other (less expensive) options have been tried, and we think appeal to the critical "3Ps" (i.e. patient, physician and payer) in the healthcare treatment chain will be sufficiently satisfied to drive meaningful demand shortly following launch.

InFoods Modeling Assumptions

Market opportunity: IBS is often very difficult to diagnose and symptoms can differ individual-to-individual. This heterogeneity means that the market opportunity for IBS-indicated therapies can also extend to other conditions including symptom-similar diseases (particularly inflammatory bowel diseases) such as Crohn's, chronic idiopathic constipation (CIC), ulcerative colitis and celiac disease. Our ancillary market size estimates exclude patients comorbid with IBS (i.e. these represent incremental populations). The following is our estimates of the total U.S. market opportunity for InFoods

Total U.S. market opportunity: 58M people

- U.S. IBS total market size: 45M people (18M mild, 16M moderate, 11M severe)
  - IBS-M: 13.5M
  - IBS-C: 13.5M
  - IBS-D: 18M
- U.S. ancillary conditions market size: 13M people
  - Crohn's: 4M
  - CIC: 2M
  - Ulcerative colitis: 4M
  - Celiac disease: 3M

Initial "reachable" market: while we calculate the total U.S. market for InFoods at approximately 58M people, the initial "reachable" market is likely only a fraction of that as most people with IBS do not visit their doctor for it. According to the International Foundation for Functional Gastrointestinal Disorders, there are only about 3.5M physician visits each year for IBS – which we use as the initial reachable IBS market. For the ancillary markets, we assume the initial reachable market is 30% of the total, or (13M x .30) = 3.8M. However, we also assume that if InFoods can demonstrate incremental efficacy that it will encourage a significantly greater number of people to visit their doctors. We estimate that can increase the size of the reachable market by 15% per year for at least the first five years.

Frequency of InFoods Testing Per Patient: BMRA expects InFoods will be most effective when patients return to be re-tested 2 to 3 times per year which allows for optimizing efficacy through diet re-adjustments. We assume an average of 2.5 visits per patient per year.

Pricing / Margin: we should have a better idea of pricing expectations with more information relative to expected reimbursement. We believe cost (i.e. COGS) of the test and related processing will be relatively inexpensive, particularly with volume, as the technology is largely commoditized and widely available. We currently assume per-test pricing of $150 and COGS (i.e. material expense and processing) of $30 and gross profit $70.

Commercialization Partner: based on our discussions and certain feedback, we think it is likely that BMRA will look to out-license U.S. commercialization, similar to what they did with Telcon in S. Korea. We think out-licensing is also a safer move from a financial standpoint. We hope to know more about potential

commercialization plans over time but, until then, we assume a royalty rate of 15% for the U.S. market (i.e. same rate as Telcon deal).

Market Penetration: given the drawbacks of IBS drugs and pent-up demand for more effective alternatives, we think that if InFoods demonstrates significant incremental clinical benefit at what we expect to be a relatively low cost, it has the potential to see fairly rapid widespread adoption. Additionally, no drugs are indicated to treat IBS-M (~30% of all IBS cases) – which means InFoods uptake among these patients could be particularly robust. We think that InFoods has the potential to capture 10% of the reachable market within the 3rd full-year following launch in the U.S. and 15% by year-5.

Timelines: BMRA is ballparking 9 – 14 months for the (n=180) initial "endpoint-finding" study. While we do not know what to expect in terms of the size or duration of a pivotal InFoods study, our best-guess right now (using pivotal IBS drug trials as a proxy) is somewhere in the range of 300 – 400 patients per arm and 24 months from start to completion (including time for design and any FDA interaction). Assuming another 3 – 6 months for FDA filing and regulatory clearance, results in estimated InFoods U.S. launch around calendar mid-2021 (i.e. early fiscal 2022).

Risk of Unknowns: we are incorporating what could arguably be considered a conservative haircut of 70% to our revenue estimates to account for what remains a fairly sizeable number of significant unknowns. This haircut will be adjusted based on solidifying answers to these unknowns such as, for example, further substantive progress towards validation (from both a regulatory and commercial perspective) of InFoods, reimbursement, market opportunity, intellectual property protection, timelines and U.S. commercialization strategy among others.

United States Only Model

	Years on market				
	1	2	3	4	5
Assumed physician visits for (in 000s)					
IBS (C,D and M)	3,500	4,025	4,629	5,323	6,122
Ancillary conditions	3,810	4,382	5,039	5,795	6,664
Assumed penetration	0.25%	1.50%	7.00%	12.00%	15.00%
Assumed InFoods tests/patient/yr	2.5	2.5	2.5	2.5	2.5
Assumed revenue/test to distribution prtnr	$100.0	$105.0	$110.3	$115.8	$121.6
Royalty rate	15%	15%	15%	15%	15%
Partner/Distributor revenue ($000s)	**$ 685.3**	**$ 4,965.1**	**$ 27,978.3**	**$ 57,915.0**	**$ 87,415.5**
Unknowns haircut	70%	70%	70%	70%	70%
InFoods Revenue to BMRA ($000s)	**$ 205.59**	**$ 1,489.53**	**$ 8,393.48**	**$ 17,374.51**	**$ 26,224.65**

Value BMRA at $3.00/share (base business) + $4.00/share (InFoods) = $7.00/share

We use sum of the parts to value BMRA; the base business (everything except InFoods) plus InFoods. We have updated our valuation methodology now that we have incorporated InFoods into our model. We note that we are only modeling assumed U.S. InFoods sales and we do not yet model the novel h. pylori test that recently commenced clinical studies. All of our modeling and valuation-related assumptions will be updated if and when appropriate.

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 $2.90/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	19.0	15.0	13.1	1.6	14.0	1.2	1.1
OXFD	N/A	N/A	N/A	3.9	N/A	3.3	2.7
CEMI	N/A	N/A	0.0	7.6	N/A	4.8	2.7
QDEL	N/A	19.0	35.9	8.6	35.0	7.6	4.0
ABAX	57.0	50.0	42.5	5.9	33.2	7.1	6.2
Average	23.3	28.3	27.8	5.5	27.4	4.8	3.3

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	-$8.72	$3.14	$3.25	$2.33	$2.91

Value InFoods at ~$35M (~$4.00/share):

We value InFoods separately from that of the base business given the former's significantly greater growth potential. As we outlined above, we think our InFoods assumptions and related outlook/forecast are reasonable. Given the rapid growth rate and steepening revenue inflection that we estimate at approximately years 2023/2024 we think a 11x sales multiple is reasonable, particularly when looking at the ~12x trailing sales multiple Valeant paid for Salix (i.e. Xifaxin) in 2015. Applying 11x to our $8.4M 2024 forecasted InFoods revenue and discounting back to the present at 15%/year, results in InFoods present value of approximately $35M, or $4.00/share. If and when there is attrition of some of the substantive unknowns, our risk discount will similarly reduce and likely result in higher calculated InFoods value.

Our sum of the parts values BMRA at approximately $7.00/share.

APPENDIX:

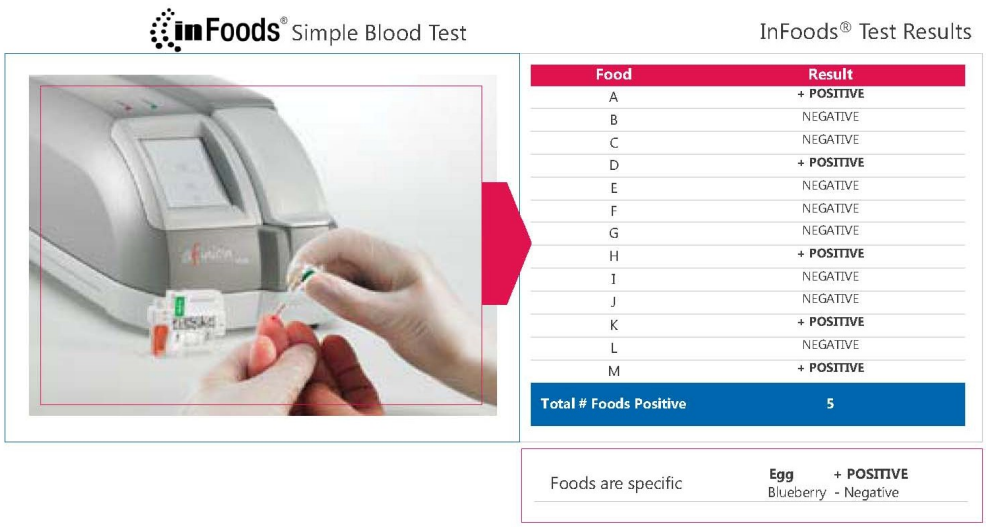
InFoods Explained

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 than 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

InFoods® Physician's Office (Point of Care) Use
(Clinical Lab Version first to be submitted)



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

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Unmet Need 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 while Viberzi may cause pancreatitis in people w/o a gallbladder. 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)	Annualized U.S TRx (M)	Comments
IBS-C	Linzess	2012	12% - 34%	7% - 13%	$382	$630**	2.90**	Diarrhea side effect (20%)
	Amitiza	2008	13%	6%	$380	$450**	1.50**	Indicated for women 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 women only. Black box warning

*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.

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
- In March 2017 FDA issued a warning against its use with that patients w/o gallbladder as it could cause serious pancreatitis
- 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 ≥ 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 filed for FDA approval (sNDA) of in March 2017. FDA approval and launch could happen in 1H 2018
- 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: Data from two (3mg and 6mg doses) phase 3 studies in IBS-C was announced in May 2017.
    - 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 events in the IBS-C phase 3 studies were diarrhea (~4%)

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	Q2A	Q3A	Q4E	2018 E	2019 E	2020 E	2021 E
InFoods TOTAL	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-	-	-	-
Legacy TOTAL	$5,792.0	$1,444.0	$1,614.0	$1,376.0	$1,530.6	$5,964.6	$6,537.6	$7,011.5	$7,521.9
YOY Growth	12.7%	2.4%	12.7%	-8.3%	5.6%	3.0%	9.6%	7.2%	7.3%
Total Revenues	**$5,791.7**	**$1,444.5**	**$1,613.6**	**$1,375.7**	**$1,530.6**	**$5,964.4**	**$6,537.6**	**$7,011.5**	**$7,521.9**
YOY Growth	12.7%	2.4%	12.7%	-8.3%	5.6%	3.0%	9.6%	7.2%	7.3%
Cost of Goods Sold	$3,769.9	$929.9	$1,107.4	$910.3	$994.9	$3,942.6	$3,987.9	$4,242.0	$4,513.2
Gross Income	**$2,021.9**	**$514.6**	**$506.2**	**$465.4**	**$535.7**	**$2,021.9**	**$2,549.7**	**$2,769.5**	**$3,008.8**
Gross Margin	34.9%	35.6%	31.4%	33.8%	35.0%	33.9%	39.0%	39.5%	40.0%
SG&A	$1,845.8	$452.0	$522.5	$434.7	$466.8	$1,876.0	$2,092.0	$2,159.5	$2,301.7
% SG&A	31.9%	31.3%	32.4%	31.6%	30.5%	31.5%	32.0%	30.8%	30.6%
R&D	$1,130.7	$288.6	$272.4	$353.6	$558.0	$1,472.6	$4,212.0	$3,567.0	$2,622.0
% R&D	19.5%	20.0%	16.9%	25.7%	36.5%	24.7%	64.4%	50.9%	34.9%
Operating Income	**($954.6)**	**($226.0)**	**($288.7)**	**($322.8)**	**($489.1)**	**($1,326.7)**	**($3,754.4)**	**($2,957.0)**	**($1,914.9)**
Operating Margin	-16.5%	-15.6%	-17.9%	-23.5%	-32.0%	-22.2%	-57.4%	-42.2%	-25.5%
Total Other Income (Expense)	$46.1	$19.0	$20.1	$0.4	$3.4	$42.8	$28.0	$30.0	$25.0
Pre-Tax Income	**($908.5)**	**($207.1)**	**($268.7)**	**($322.5)**	**($485.7)**	**($1,283.9)**	**($3,726.4)**	**($2,927.0)**	**($1,889.9)**
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)**	**($268.7)**	**($322.5)**	**($485.7)**	**($1,283.9)**	**($3,726.4)**	**($2,927.0)**	**($1,889.9)**
YOY Growth	-39.4%	74.7%	21.6%	5.3%	15.4%	41.3%	190.2%	-21.5%	-35.4%
Net Margin	-15.7%	-14.3%	-16.6%	-23.4%	-31.7%	-21.5%	-57.0%	-41.7%	-25.1%
EPS	**($0.11)**	**($0.02)**	**($0.03)**	**($0.04)**	**($0.06)**	**($0.15)**	**($0.41)**	**($0.31)**	**($0.20)**
YOY Growth	-44.5%	70.8%	18.7%	4.0%	14.4%	37.6%	171.4%	-22.9%	-36.8%
Diluted Shares O/S	8,330	8,511	8,520	8,556	8,635	8,556	9,150	9,325	9,525

Brian Marckx, CFA

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