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Zacks Small-Cap Research

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Biomerica Inc. (BMRA-NASDAQ)

BMRA: InFoods Clinical Trial Advances, Further Step Towards Potential FDA Clearance

As a diagnostic-guided therapy (not a drug), InFoods® does not have the side effects drugs often have and can be used alone and/or as part of a drug therapy program. In the U.S., IBS-related diseases impact an estimated 45+ million people.

OUTLOOK

Patient enrollments in the InFoods® IBS endpoint clinical trial are expected to be completed by the end of April 2021 and BMRA is optimistic that results could lead to potential partnership discussions with global Big Pharma, health sciences and/or medical device companies. The study advances inFoods on the path to potential FDA clearance following a subsequent final pivotal trial. Separately, earlier this year BMRA received a 2nd U.S. patent for InFoods, which we believe expands the potential applications and use of the platform.

Current Price (12/15/20)	$5.73
Valuation	**$9.50**

SUMMARY DATA

52-Week High	**$16.00**
52-Week Low	**$2.05**
One-Year Return (%)	**109%**
Beta	**-0.49**
Average Daily Volume (sh)	**141,206**
Shares Outstanding (mil)	**12**
Market Capitalization ($mil)	**$68**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**5**
Insider Ownership (%)	**26**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**0.0**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2021 Estimate	**N/A**
P/E using 2022 Estimate	**N/A**
Zacks Rank	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med Tech Diagn.**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Aug)	Q2 (Nov)	Q3 (Feb)	Q4 (May)	Year (May)
2019	1.27 A	1.50 A	1.12 A	1.20 A	5.20 A
2020	1.19 A	1.60 A	1.18 A	2.73 A	6.69 A
2021	1.14 A	1.79 E	1.25 E	1.85 E	6.03 E
2022					6.54 E

Price/Sales Ratio (Industry = 2.5x)

	Q1 (Aug)	Q2 (Nov)	Q3 (Feb)	Q4 (May)	Year (May)
2019	-$0.05 A	-$0.05 A	-$0.07 A	-$0.08 A	-$0.26 A
2020	-$0.05 A	-$0.05 A	-$0.09 A	-$0.04 A	-$0.23 A
2021	-$0.14 A	-$0.05 E	-$0.03 E	-$0.08 E	-$0.30 E
2022					-$0.26 E

Quarters might not sum due to rounding & share counts

Disclosures begin on page 10

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KEY POINTS

- Last week BMRA announced that it is nearing completion of patient enrollment in the InFoods® IBS endpoint clinical trial. As a diagnostic-guided therapy (not a drug), InFoods does not have the side effects drugs often have and can be used alone and/or as part of a drug therapy program.

- Patient enrollments are expected to be completed by the end of April 2021 and BMRA is optimistic that results from the endpoint trial will lead to potential partnership discussions with health sciences, Big Pharma and medical device companies. The study also advances inFoods on the path to potential FDA clearance following a subsequent final pivotal trial.

- Earlier this year, BMRA received a 2nd U.S. patent for InFoods, which we believe expands the potential applications and use of the inFoods platform. In the U.S., IBS-related diseases impact an estimated 45+ million people (according to IFFGD) and the total direct plus indirect annual domestic cost of IBS has been estimated at $30 billion, according to the Journal of American Managed Care.

- Separately, BMRA's focus in 2020 has included extending its expertise and technology to develop and commercialize COVID-19 diagnostics. The company has developed two types of serological diagnostic tests for COVID-19, a rapid diagnostic test (RDT) and an enzyme-linked immunosorbent assay (ELISA), and is also developing an antigen test. We believe this both creates a new revenue stream and also offers proof-of-concept of the versatility and applicability of the company's technology and IP.

- BMRA hired an experienced industry executive to assume the role of CFO following the recent retirement of its longstanding CFO. The new CFO has extensive industry experience. Management is optimistic that he can help support the company's anticipated growth as it advances inFoods and extends its expertise and technologies to other applications, as it has done with the recent introduction of COVID-19 diagnostic tests.

INFOODS COMPLETING CLINICAL STUDY PATIENT ENROLLMENT

Biomerica (NASDAQ: BMRA) announced last week that it is nearing completion of patient enrollment in the endpoint clinical trial for the InFoods® Irritable Bowel Syndrome (IBS) diagnostic-guided therapy platform. The study is a double-blinded, randomized, controlled clinical trial designed to test and verify that the Biomerica InFoods® IBS platform can manage the symptoms and pain of patients diagnosed with IBS.

IBS symptoms frequently are triggered when people eat specific foods. Trigger foods vary from patient-to-patient and are specific for each individual patient. For instance, one person might be able to consume broccoli with no problem but milk triggers discomfort and symptoms, while another person might be fine with milk but cannot tolerate broccoli. Eliminating trigger foods from the patient's diet is expected to alleviate IBS symptoms, discomfort and pain. Utilizing an antibody-guided blood test, the InFoods® technology identifies foods that trigger IBS symptoms and pain in order to help create a dietary regime designed to minimize ongoing occurrence of symptoms.

It is important to bear in mind that the InFoods platform is a diagnostic-guided therapy, *not a drug.* Therefore, it has no side effects, as drugs often have, and can be used by itself and/or incorporated as part of a drug therapy program to treat IBS patients without causing additional side-effects. It is designed to enable patient-specific guided dietary regimens to help alleviate IBS symptoms, as noted.

The company anticipates that results from the endpoint trial will lead to discussions with health sciences, pharmaceutical and medical device companies worldwide for potential partnering opportunities on

inFoods. The study also advances the inFoods path to potential FDA clearance following a subsequent final pivotal trial.

Several prominent medical centers are participating in the study, including the Mayo Clinic, Beth Israel Deaconess Medical Center, Houston Methodist, University of Texas Health Science Center and the University of Michigan. Patient enrollments are expected to be completed by the end of April 2021.

The objective of the clinical endpoint trial is to validate key elements and provide the selection of a proper endpoint of a proposed larger and final FDA pivotal trial. BMRA expects to launch the pivotal trial once the clinical endpoint trial is completed successfully. The design of the InFoods® IBS product clinical endpoint study has already received a non-significant risk determination from the FDA; BMRA will not need to submit an investigational device exemption (IDE) for the InFoods® IBS product study.

InFoods® Diagnostic Platform Opportunities Expand

Earlier this year, the U.S. Patent and Trademark Office (USPTO) issued a Notice of Allowance for Biomerica's second U.S. patent on the InFoods® technology platform for the treatment of patients suffering from Irritable Bowel Syndrome (IBS) and other gastrointestinal diseases.

We believe the USPTO action will expand the potential applications and use of inFoods. It covers the method allowing doctors to identify specific foods (pork, milk, shrimp, broccoli, chickpeas, and others). When patients eliminate the foods that test positive for triggering IBS and/or other gastrointestinal distress, generally their symptoms such as constipation, diarrhea, bloating, severe cramping, pain and indigestion ease or are eliminated entirely.

This is the second allowed patent BMRA has received as it applies for broad patent protection for a test panel and method to determine patient specific foods that might trigger IBS symptoms. BMRA has several additional U.S. and international patent applications pending that cover other claims pertaining to the InFoods platform to increase its coverage and scope. Separately, the company also recently announced that it had received its first patent for inFoods in Japan. An estimated roughly 19 million people in Japan suffer from IBS, according to management.

BMRA has other U.S. and international patent applications in process to protect the InFoods IBS platform. Overall, BMRA has filed more than 100 international and Patent Cooperation Treaty (PCT) patents and has 22 provisional and non-provisional patents currently filed with the U.S. Patent and Trademarks Office relevant to the InFoods platform, COVID-19 tests and other products.

Addressable Market

IBS is a chronic condition affecting the large intestine that is characterized by recurrent abdominal pain or bowel symptoms. Symptoms include, among others, cramping, abdominal pain, bloating, gas and diarrhea and/or constipation. IBS is among the most common diseases of the gastrointestinal tract, according to the NIH. IBS-related diseases impact an estimated more than 45 million Americans. The total direct and indirect cost of IBS has been estimated at $30 billion annually in the U.S. market alone, according to the *Journal of American Managed Care*.

EXTENDING TECHNOLOGY PLATFORM TO TEST FOR COVID-19

With COVID-19 cases spiking in many markets, the need to test for a variety of reasons, such as ahead of travel or to attend school in-person or at nursing homes, continues to grow. For example, many port authorities have offered incoming travelers the option to test-out of mandatory extended quarantine requirements otherwise required of most travelers: This means that travelers need to get a COVID-19 test before they travel and again upon arrival at their destination.

Since March 2020, BMRA has focused on extending its expertise and technology to develop, commercialize and market COVID-19 antibody tests. The company has developed two types of serological diagnostic tests for COVID-19, a rapid diagnostic test (RDT) and an enzyme-linked immunosorbent assay (ELISA).

In April 2020, Biomerica announced that it had signed two non-exclusive license agreements with New York's Mount Sinai Icahn School of Medicine to license technologies from Mount Sinai in order to scale up a laboratory version COVID-19 serological test. According to the *MIT Technology Review*, researchers at Mount Sinai's Icahn School of Medicine have developed technology for testing to detect antibodies against coronavirus in the blood of someone who has been exposed to the virus. The presence or absence of antibodies can determine whether the person has had exposure.

BMRA's test uses the ELISA microplate format that can run on the existing open system equipment installed in most domestic hospitals and clinical laboratories. Because the format is widely used, it is expected to make the BMRA ELISA format test easy to adopt. If the new ELISA COVID-19 test proves successful, BMRA believes that commercial sales could begin in the near-term, particularly given the significant unmet need for testing for the disease. Under the license agreements, once the test has been launched commercially, BMRA will pay royalties to Mount Sinai based on a percentage of gross sales. The company believes its ELISA test has a competitive advantage in simplifying the blood sample collection process in a proprietary way. Biomerica has sufficient capacity at its California production facility to produce more than one million tests monthly in the ELISA microplate format.

The company also launched a new high-volume production point-of-care version of an RDT COVID-19 Rapid Test, using a proprietary card system that eliminates most plastic. It is a serology, finger prick blood test to detect antibodies indicating if the person being tested has had an immune response to the novel Corona Virus (SARS CoV-2). The test can determine if the person has had exposure to the virus even if he or she is asymptomatic. The high-volume production version of the test is intended for larger customers doing high-volume screenings. Because the company has eliminated much of the plastic in the high-volume version, it is also considered to be *greener* with regards to the environment.

BMRA received a Conformitè Europëenne (CE) Mark to market the high-volume test in the EU. The CE mark shows that the test complies with the EU requirements and safety standards. Biomerica received the CE mark on May 5, 2020.

The company also seeks FDA approval for commercial sales in the U.S. pursuant to the FDA's EUA (Emergency Use Authorization) process. In February 2020, FDA issued *Immediately in Effect Guidance* on diagnostics testing for the coronavirus. The EUA process enables the FDA to move rapidly in an emergency situation such as the coronavirus pandemic. Specifically, it allows the FDA to authorize unapproved medical products or new uses of approved medical products to diagnose, treat or prevent serious diseases in an emergency situation when no approved alternatives are available. This enables BMRA to file for expedited clearance with the FDA under the EUA process.

Potential COVID-19 Antigen Test

We believe the need for COVID-19 testing will persist for the foreseeable future. A recent Canadian study published in Diagnostics 2020 indicates that BMRA's RDT test showed 100% sensitivity and 100% specificity and was included in the rankings of top-performing COVID-19 serological tests based on independent evaluations of sensitivity/specificity.

In addition to the antibody tests, BMRA is also developing an antigen test to determine whether a person actively has the virus. As the CDC notes, antigen tests are immunoassays designed to detect the presence of a specific viral antigen implying an active viral infection. With the vaccines that are being commercialized showing little-to-no benefit for a subset of the overall population, an antigen test would enable people to confirm that the test was beneficial for them.

MANAGEMENT & BOARD CHANGES

Earlier this year, BMRA announced that its longstanding CFO, Janet Moore, intended to retire. She had been with the company for decades. With her retirement, the company hired an experienced industry executive. Steve Sloan assumed the role of CFO effective September 3, 2020. Prior to joining Biomerica, he spent 13 years at General Electric and after that, ten years at medical device company Medtronic, where he served in several executive capacities and most recently was a divisional finance director.

BMRA also announced the addition of Ms. Cathy Coste as a new, independent member of the Board or Directors. Cathy will join the Board effective September 3, 2020. Ms. Coste has also been elected by the Board to chair the Board's Audit Committee, and to be a member of the Nominating and Corporate Governance Committee. Cathy Coste is a Senior Partner at Deloitte and Touche, LLP, where she has spent thirty-two years in audit and advisory services to global corporations.

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, we believe, 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.

An estimated 40+ million people suffer with IBS symptoms in the U.S. Symptoms can be triggered by consumption of specific foods and the particular trigger food varies from case to case. In the U.S., the total cost (direct + indirect) to treat and because of IBS is an estimated $30 per annum.

We value BMRA’s base business at $2.50/share. We estimate rapid growth for inFoods commencing in approximately 2023 – 2024. Applying an 11x multiple to our $8.4M 2024 forecasted InFoods revenue and discounting back to the present at 14%/year, results in InFoods present value of over $70M, or about $7.00/share. We believe our forecast could be conservative particularly as the company’s patent portfolio expands.

We also believe that the incremental value of the company’s COVID-19 tests could add some $2.00-$3.00 per share, given the ongoing demand for testing of this disease and the frequency with which tests will be administered to certain individuals. For example, at many universities, college students are being required to test at least twice monthly in order to be allowed to remain on campus. It is still early, but estimates of the size of the COVID-19 testing market range from $8.5 billion to over $11 billion by 2026-27. If BMRA captures less than 0.1% of the market, we believe it could translate into an incremental nearly $3 per share of valuation that is not included in our current valuation.

FINANCIAL RESULTS

FY 1Q21 Results

BMRA's 1Q FY 2021 sales were $1.1 million compared to $1.2 million registered in 1Q FY 2020, representing a 4.2% year-over-year decline primarily reflecting lower sales to some distributors and certain orders being delayed. Management believes that sales of non-COVID-19 products were hurt by the COVID-19 pandemic. This impact was partially offset by roughly $290,000 in higher contract manufacturing and COVID-19 test sales.

The 1Q FY 2021 gross margin fell to 16.0% from 30.8%. Margins on product sales were unchanged. However, due to the negative impact of COVID-19 on sales of non-COVID-19 products, BMRA ran its manufacturing facilities below the usual level of production capacity usage. In turn, this had a negative impact on margins.

S,G&A more than doubled to $1.2 million from $506,397 in the year earlier 1Q. This year-over-year increase primarily reflected higher legal expense related to an SEC inquiry regarding sales of COVID-19 products, as well as higher consulting fees and personnel expense to support anticipated growth, among other factors. The SEC has taken a proactive stance regarding companies that publish potentially misleading claims related to COVID-19 inflating revenue and earnings or mislabeling expenses, among other factors. The SEC has, in fact, filed complaints against many companies that failed to back up their COVID-related claims. However, BMRA's COVID-19 test has been evaluated and ranked by a study published in Diagnostics 2020, has received a CE mark authorizing sales in the EU and is sold through third-party distributors, as noted.

R&D expense increased to $674,693 from $506,397, or about 82% year-over-year, largely reflecting costs related to clinical trials and validating the COVID-19 tests. At the end of 1Q FY 2021 (August 2020), BMRA had cash & equivalents of $7.0 million.

FY 2020 Results

BMRA registered FY 2020 (FY ends May 31) net sales of $6.7 million, up 28.7% year-over-year versus $5.2 million registered in FY 2019. The increase was driven primarily by sales of COVID-19 tests primarily in 4Q FY 2020. This was offset partially by revenue declines related to business disruptions related to the COVID-19 pandemic. Net sales were $2.7 million in 4Q 2020, up from $1.2 million in the prior for FY 4Q.

FY 2020 COGs increased to $4.9 million from $3.9 million on the higher revenue base. As a percentage of sales, COGs declined to 73.4% from 75.2% primarily reflecting higher margins on the above-noted COVID-19 products and the gross margin increased to 26.6% compared to 24.8% in FY 2019.

S,G&A expense increased to $2.2 million in FY 2020 from $2.0 million in FY 2019, reflecting increased legal and consulting fees and higher personnel costs as BMRA expands and strengthens its management and sales and marketing staff to support anticipated growth. Moreover, the COVID-19 initiative and focus on the core business, with the above-noted second patent for the inFoods platform, also led to higher patent-related and other legal expense. Reflecting R&D to support the launch of the above-noted COVID-19 products and InFoods® clinical trials, R&D expense advanced to $1.9 million from $1.7 million in FY 2019.

RECENT NEWS

- On December 9, 2020, BMRA announced that it expects to complete enrolling patients in the InFoods® IBS diagnostic-guided therapy (DGT) clinical trial by the end of April 2021.
- The company reported FY 2020 results on September 1, 2020.
- On 8/31/2020, BMRA announced that its CFO intended to retire.
- BMRA received a second Notice of Allowance for inFoods on August 12, 2020.
- On July 22, 2020, the company filed a shelf registration.
- University of Texas Health Science Center joined the InFoods clinical trial on June 29, 2020.
- BMRA filed for FDA Emergency Use Authorization (EUA) for its COVID-19 test on June 16, 2020.
- The Mayo Clinic joined the inFoods clinical trial on June 1, 2020.
- BMRA received the CE mark authorizing commercial sales of the high-volume COVID-19 test in the EU on May 5, 2020.
- On April 2, 2020, BMRA announced new licensing agreements with Mount Sinai in New York.

RISKS

We believe risks include those outlined below, among others.

- BMRA might not be able to obtain regulatory approval of its developing product portfolio as quickly as it expects or at all.
- In order to continue advancing its developing pipeline, BMRA might need additional funding that could be dilutive to existing shareholders.
- The company could incur unanticipated costs in commercializing its products.
- Discussions with a potential inFoods partner could take longer than management expects or not result in an agreement.
- Competition could increase.

FINANCIAL MODEL

Biomerica Income Statement & Projections
($ thousands except per share data)

	2019 A	1Q20	2Q20	3Q20	4Q20	2020 A	1Q21A	2Q21	3Q21	4Q21	2021 E	2022 E	2023 E
InFoods TOTAL	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$206	$1,490
YOY Growth													
Legacy TOTAL	$5,201	$1,194	$1,597	$1,177	$2,725	$6,693	$1,144	$1,789	$1,248	$1,845	$6,025	$6,339	$6,789
YOY Growth	-6.5%	-6.2%	6.4%	-6.7%	133.7%	28.7%	-4.2%	12.0%	6.0%	-32.3%	10.9%	5.2%	7.1%
Total Revenues	5,201	1,194	1,596	1,177	2,725	6,693	1,144	1,789	1,248	1,845	6,025	6,544	8,278
YOY Growth	-6.5%	-6.2%	6.4%	-6.7%	133.7%	28.7%	-4.2%	12.0%	6.0%	-32.3%	10.9%	8.6%	26.5%
Cost of Goods Sold	3,909	827	1,128	965	1,991	4,911	961	1,216	848	1,048	4,073	4,241	5,166
Gross Income	1,292	367	469	212	734	1,782	183	572	399	798	1,952	2,304	3,113
Gross Margin	24.8%	30.8%	29.4%	18.0%	26.9%	26.6%	16.0%	32.0%	32.0%	43.2%	32.4%	35.2%	37.6%
SG&A	2,026	506	554	654	561	2,274	1,165	751	524	98	2,537	2,894	3,301
% Revenue	39%	42%	35%	56%	21%	34%	102%	42%	42%	44%	42%	44%	40%
R&D	1,679	371	405	473	662	1,910	675	429	299	1,598	3,002	2,748	2,027
% Revenue	32%	31%	25%	40%	24%	29%	59%	24%	24%	24%	50%	42%	24%
Operating Income	(2,413)	(510)	(490)	(915)	(489)	(2,403)	(1,656)	(608)	(424)	(898)	(3,587)	(3,338)	(2,216)
Operating Margin	-46%	-43%	-31%	-78%	-18%	-36%	-145%	-34%	-34%	-49%	-60%	-51%	-27%
Total Other Income (Expense)	44	4	5	54	9	71	8	5	55	(42)	25	40	71
Pretax Income	(2,369)	(506)	(485)	(861)	(480)	(2,332)	(1,648)	(604)	(370)	(940)	(3,562)	(3,298)	(2,145)
Tax expense (benefit)	24	1	-	-	7	7	1	-	-	-	-	-	-
Tax Rate	nm	nm	-	-	-	nm	-	-	-	-	-	-	-
Net Income	(2,393)	(506)	(485)	(861)	(487)	(2,339)	(1,649)	(604)	(370)	(940)	(3,562)	(3,298)	(2,145)
EPS	($0.26)	($0.05)	($0.05)	($0.09)	($0.04)	($0.23)	($0.14)	($0.05)	($0.03)	($0.08)	($0.30)	($0.26)	($0.16)
Diluted Shares O/S	9,213	9,744	9,817	9,890	11,214	10,166	11,748	11,848	11,888	11,928	11,853	12,853	13,253

Source: Company reports, Zacks estimates

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