BIOMERICA INC
Form 8-K
August 10, 2016

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C.

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the

Securities Exchange Act of 1934

August 10, 2016

Date of Report (date of earliest event reported)

BIOMERICA, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	0-8765	95-2645573
(State or Other Jurisdiction of Incorporation	(Commission File Number)	(IRS Employer Identification Number)

17571 Von Karman Ave.

Irvine, California 92614

(Address of Principal Executive Offices

Including Zip Code)

949-645-2111

(Registrant s Telephone Number,

Including Area Code)

_____

(Former Name or Former Address if Changed

Since Last Report)

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Item 8.01. Other Events

Below is an update for shareholders on the Company s InFoods IBS product:

Dear Fellow Shareholders:

The purpose of this letter is to give you an update on our progress in the commercialization of our new IBS diagnostic guided therapy product. We have made significant headway on our strategies to date, which continue to focus on attracting key opinion leaders and experienced executives who will assist us in submitting for FDA clearance and set up the foundations for worldwide distribution of the product. We have been very selective and strategic on the individuals we have approached to join our team. Many shareholders and others have asked How did we attract such world class IBS doctors and business leaders to our team ? The answer is after they reviewed our data and science they all believed in our product and its potential to help the millions of IBS sufferers worldwide.

We are moving forward with confidence that knowledgeable companies should see the same value and want to license our product. We recently signed our first licensing agreement for the product with a company that approached us for a license in South Korea. We believe that the fastest way for us to get worldwide distribution is through licensing. To execute this strategy, we are excited to have added Dr. Mark Sirgo to our Board of Directors. Dr. Sirgo was on the board of directors for Salix Pharmaceuticals and instrumental in growing Salix into a major international GI company which he then helped sell to Valeant for $11.1 billion. Dr. Sirgo has extensive knowledge of the companies in the IBS space and their strategies. To further strengthen our ability to license the product, we are delighted to have added Ned Barnholt to our Strategic Advisory Board to help guide our commercialization. Ned is a world class executive who is currently Chairman of the Board of KLA-Tencor, a company with a market cap of $12 billion, and currently serving on the Board of Directors of eBay and Adobe. He previously served as CEO and Chairman of Agilent Technologies. We believe we are now well positioned to be able to seek the right marketing partners for our product. Below please find a more detailed explanation of our business plans and strategies.

The Product

Our InFoods® IBS product identifies patient specific foods that when removed may alleviate an individual's IBS symptoms. This patent pending diagnostic guided therapy is designed to allow for a patient specific guided dietary regimen to improve Irritable Bowel Syndrome (IBS) outcomes. The point-of-care product is being developed to allow physicians to perform the test in-office using a finger stick blood sample while a clinical lab version of the product will be the first for which we will seek regulatory approval. A billable CPT code that can be used by both clinical labs and physicians' offices is available for InFoods® diagnostic products. Since the InFoods® product is a diagnostic guided therapy and not a drug, it has no drug type side effects.

FDA Clearance

We have assembled a Scientific Advisory Board made up of some of world s leading Gastroenterology physicians who specialize in IBS in the world and have been using their guidance to work on the proper FDA regulatory path for clearance of the InFoods® product. All of them have reviewed the science behind our product. In addition, all of them have extensive experience in running clinical trials and clinical trial design for IBS drugs, which will be of importance as we progress in the development of the InFoods® product.

Our scientific advisory board is made up of the following members:

Dr. Douglas Drossman: He 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. When Biomerica approached Dr. Drossman, he was initially skeptical. However, as he reviewed the science behind Biomerica s technology he became interested and joined the Scientific Advisory Board as Chairman.

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.

FDA Update

Recently the U.S. Food and Drug Administration (FDA) has determined that the proposed clinical study to validate performance of our InFoods IBS product is a nonsignificant risk (NSR) device study. This means the Company will not be required to submit an investigational device exemption (IDE) for the InFoods IBS product clinical study. We are pursuing a de novo 510(k) rather than a PMA (Premarket Approval Application). De novo clearance is faster and less expensive than the PMA route, which is the most stringent type of device marketing application required by FDA.

Commercialization

Just as we have done with our scientific advisory board, we have recruited experienced and respected individuals to help guide possible distribution, licensing and commercialization opportunities.

South Korea

We recently announced that we entered into an exclusive license agreement with Celtis Pharm Co. Ltd of South Korea granting Celtis an exclusive license to market and sell Biomerica's new InFoods® IBS (Irritable Bowel Syndrome) products in Korea. Under the terms of the agreement, Celtis shall pay up to $1.25 million in exclusivity fees to Biomerica based on certain milestones including receipt of US FDA clearance. In addition to the exclusivity fees, a royalty fee shall be paid to Biomerica based on a percentage (in the mid-teens) of net sales of the products in Korea. The minimum royalty payments required to retain the exclusivity in Korea for the term of the agreement are $7.25 million over five years.

Biomerica also entered into a Stock Purchase Agreement with Celtis whereby Celtis has purchased 333,334 shares of the Company's restricted common stock at the purchase price of $3.00 per share for an aggregate purchase price of $1,000,002.

The exclusive territory under this license agreement is the Republic of Korea (South Korea) with a possibility of future expansion into other territories in Asia if mutually agreed upon terms are reached. The term of the exclusivity agreement is five years with an additional two years for Celtis to receive Korean FDA clearance and begins with the date Biomerica receives final clearance for sale of the InFoods® IBS products in the United States. The agreement may be cancelled if Biomerica has not obtained final clearance for sale of the Products in the United States from the

United States FDA on or before December 31, 2017.

Dr. Mark Sirgo added to the Board of Directors

We recently added Dr. Mark Sirgo to our board of directors. His expertise and experience in the market we are pursuing speaks for itself. Dr. Sirgo served on the Board of Directors and as Chairman of the Compensation Committee of Salix Pharmaceuticals, Inc. a specialty pharmaceutical company specializing in gastrointestinal products since 2008 until its sale in 2015. He was strategically involved in the company's sale to Valeant for over $11.1 billion in an all cash deal. He is the current CEO, President and Director of BioDelivery Sciences International, Inc (BDSI), a specialty pharmaceutical company where he has overseen the approval of three drug products since 2009. He has more than 30 years of experience in the pharmaceutical industry, including clinical drug development, marketing, sales, and business development. He spent 16 years in a variety of positions of increasing responsibility in both clinical development and marketing at Glaxo, Glaxo Wellcome, and GlaxoSmithKline including Vice President of International OTC Development and Vice President of New Product Marketing. Dr. Sirgo was responsible for managing the development and FDA approval of Zantac 75 for episodic heartburn among other accomplishments.

New Strategic Advisory Board & Ned Barnholt

We recently formed a new Strategic Advisory Board is to help guide our licensing direction and discussions. Ned Barnholt, the first member on the board, has a vast knowledge of medical commercialization and distribution.

Ned Barnholt: is currently chairman of the KLA-Tencor Corporation (Nasdaq: KLAC approximate market cap: $12 billion) and serves on the board of directors of eBay, Inc. 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).

We believe we now have the team in place to guide and assist us during the regulatory process for the InFoods® product and to help guide in finding possible commercialization partners. I want to thank our shareholders and other stakeholders who have supported us. We are committed to improving our performance and continuing our transformation.

Respectfully,

Zackary Irani

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Biomerica, Inc

Dated: August 10, 2016

By: /s/ Zackary S. Irani
Zackary S. Irani
Chief Executive Officer