

With Vayarin® addressing Lipid Imbalances Associated with ADHD and Vayacog® the lipid imbalances associated with Early Memory Impairment, VAYA Pharma, Inc. – USA is using clinically proven Medical Foods to address areas of Unmet Needs



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“For me, learning about medical foods has been a new and rewarding experience. I did not realize what an incredible industry this is and how important these products are for the many unmet needs that are out there within so many disease areas... I am thrilled to be part of a company that can adapt fast, innovate constantly and is at the same time changing the lives of so many people.” - Michelle Cuccia

CEOCFO: *Ms. Cuccia, according to the VAYA website, you are forging innovation through science and nature. Would you tell us about that?*

Ms. Cuccia: VAYA Pharma is a company that specializes in medical foods. Medical foods are uniquely formulated to support disease states through clinical nutrition and are backed up by robust science. We say that we are forging science through nature because all the ingredients in our products come from natural sources. We are using the ingredients found in nature and specially formulating them to manage disease states that have important unmet nutritional needs. We at VAYA take enormous pride in the scientific rigor we put behind our products because it's something that differentiates us from other companies in the nutritional space. All of our products are studied via placebo controlled, double-blinded, clinical trials in order to support the clinical efficacy and safety in patients.

CEOCFO: *What are medical foods and when are they used; when should they be used?*

Ms. Cuccia: Medical foods are intended to be used for the dietary management of a disease that has distinctive nutritional needs that cannot be met by diet alone. They need to be taken under medical supervision. As an example, VAYA's medical foods are used in conditions where there is a known lipid, or healthy fat, imbalance, such as in Attention Deficit Hyperactive Disorder (ADHD) and Early Memory Impairment (EMI). It is not possible to manage these nutritional deficiencies by changing diet alone or taking supplements, since there are many causal factors, including nutrition, genetics, and absorption, among others. VAYA's medical foods contain different types of specialized lipids (or healthy fats) enriched with different types of Omega-3 fatty acids. These specialized lipids are brought together via a

proprietary enzymatic process that allows for the delivery of these important healthy fats across the blood-brain barrier. A patient should take VAYA's products when they are looking for a drug-free product, that has been clinically studied, is made of high quality ingredients and has virtually no side effects.

CEO CFO: *Whether it is Vayarin® or Vayacog® would a doctor typically suggest this, might a more holistic healthcare professional suggest it or would a person come upon it on their own?*

Ms. Cuccia: Our business model at VAYA is a mix between a pharmaceutical model and a consumer model. We have a national field force of sales representatives that visits and educates physicians and other healthcare providers, such as psychologists and pharmacists, on our products. We ask physicians to write a first recommendation (e.g. can be a prescription) for our products to ensure that patients are under medical supervision, as is mandated by the FDA for medical foods. With that recommendation the patient can go to a local pharmacy and ask the pharmacist for the products behind the counter. The patients can also buy the products directly from VAYA through www.vayadirect.com without a prescription, only after they confirm online that they are under medical supervision. We believe that healthcare providers play an important role in the use of our products and should always be involved in any recommendations or changes to patients' healthcare plan. In order to partner with healthcare providers to best support patient outcomes, we recently launched an online Patient Adherence program, where patients can easily process product refills, get reminders to keep them more compliant, and receive ongoing educational information, health management tools and discounts.

CEO CFO: *How is a person able to measure the efficacy of the products, given they may be doing other things as well?*

Ms. Cuccia: This is one of the most important differentiating factors in our products and at the same time one of our toughest business challenges. Because our products are drug-free, based on natural ingredients, they act more subtly in the body. Imagine having a lipid imbalance or a lipid deficiency in your brain and you start taking our medical foods. What is happening day-in and day-out is that slowly, but surely, the lipids in your brain start to regenerate making your brain cells more robust, more communicative and overall healthier. However, this process does not happen overnight. In the case of Vayarin® and Vayacog®, it can take thirty to ninety days for the product to build up in your brain and for you to feel its full effect. What we have heard from patients through ongoing testimonials is that once the effect is achieved they feel sharper, more focused, but also more like themselves, unlike the way they feel when they are on prescription medicines. Many prescription drugs are effective and act quickly, but they also wear-off and can have difficult to manage side-effects. With our products it is different; they are drug-free, so the effect is subtler and takes more time, but once the imbalances are restored the effect lasts 24 hours a day, 7 days a week and you feel like you are more yourself: a more focused, empowered and healthier self.

CEO CFO: *Are doctors and the general public becoming more receptive to medical foods and is there a lot of education to be done?*

Ms. Cuccia: There is trend in the world, and it is very evident in the US, towards a more holistic and natural approach to addressing diseases. Everyone is looking to live longer and better lives, and nutrition plays a key role in trying to achieve that nowadays. The area of CNS (central

nervous system) and cognition are areas that are growing significantly in their connection with diet and nutrition. VAYA fits very well with these global trends and with what consumers and patients are looking for. Even though the medical food industry is still small compared to the pharmaceutical industry, it is one of the fastest growing sectors today. There have been quite a number of mergers and acquisitions in this space over the past 12-18 months and some larger, well-known companies are now playing an important role in this sector. I still think that as an industry we have a long way to go; we need to continue to educate healthcare providers and consumers about the role that medical foods play in the management of diseases and to help shift their treatment paradigms to always consider early on the role that a nutritional option can play. Ultimately, we know that there is a significant unmet need out there since consumers want to manage certain conditions and diseases with effective and safe drug-free options. We at VAYA are very happy to provide excellent products to fulfill that need while at the same time leveraging what is a fantastic global trend and business opportunity.

CEOCFO: *Where are your products made?*

Ms. Cuccia: Our plant is in Israel. Much of our science and raw manufacturing is done over there. We import in bulk from Israel to the United States and encapsulate and bottle here locally. Israel is well-known for its biotech industry and over-the-top science and entrepreneurship and that is where the roots of VAYA come from. Our core ingredient for Vayarin (ADHD) is krill that is harvested in the cold waters of the Antarctic Ocean. After harvesting the krill is put through a patented process where it is aggregated with other natural ingredients to make up what constitutes our final product. Vayacog is derived from cold water fish and soy and put through a similar process as Vayarin to obtain the final product. Vayarin® is a phosphatidylserine conjugated to Omega-3 fatty acids and enriched with EPA, which is known to help with emotion and mood. Vayacog® is phosphatidylserine conjugated to Omega-3 fatty acids and enriched with DHA, which is known to help with memory.

CEOCFO: *Why are VAYA products better?*

Ms. Cuccia: There are, in fact, no other products out there like VAYA's products. Our composition is patent protected in several countries and they have extensive science supporting their use for the management of ADHD and for EMI. Thousands of patients over the course of six years have used VAYA products to effectively manage their conditions in an efficacious and safe way. In addition to being drug-free, VAYA products are also made with both high quality ingredients and high production standards. Where supplements are built to support healthy people, and pharmaceuticals provide a drug option to treating conditions, VAYA medical foods fit a need to effectively and safely manage conditions through nutrition.

CEOCFO: *Do people tend to continue once they start taking your products?*

Ms. Cuccia: Many do, but this is probably one of our biggest opportunities. We have done a fantastic job historically at getting new patients to try our products, but until we launched our e-commerce site and our patient adherence program, it was difficult for us to have a close relationship and communication with our customers and to make it easy for them to refill after that first purchase. Currently we have an average patient adherence between four to six months; after that patients tend to drop off. Our recently launched patient adherence program's goal is to

increase this average timeframe. Once you make your first purchase via our call center or via our ecommerce site we automatically enroll you in our program. After enrollment you receive ongoing information about our products, can watch educational videos from physicians and real-life testimonials from patients, gain access to disease management tools, and get special discounts on refills. We will also soon set up a loyalty program so that as you use our product more and more you will be able to derive larger savings.

CEOCFO: *What surprised you as VAYA has grown and evolved as a company?*

Ms. Cuccia: I am actually relatively new to the nutrition business and to the world of medical foods. I come from a long career in the pharmaceutical industry and know first-hand that drug products are incredibly valuable, but many can also carry a heavy load of side-effects. For me, learning about medical foods has been a new and rewarding experience. I did not realize what an incredible industry this is and how important these products are for the many unmet needs that are out there within so many disease areas. What I have most enjoyed about VAYA is how fast we are able to move. I was not used to this pace; up until recently I worked at very large multinationals where making decisions and shifting paradigms and ways of working took a long time. VAYA is a small company that still has a start-up DNA at its core. We are all strategists and doers at the same time, which is spectacularly rewarding, but also a lot of hard work. Our ecommerce site is an excellent testament to that. When I first joined the company, this idea was in its inception, but we knew that it could revolutionize the way in which we interacted directly with consumers. We put all our hands to work on it and launched it in a matter of six months with all the back-end and front-end systems ready to make it run seamlessly. The adherence program that launched recently was another idea that we thought of during a phone call, when we realized that we already had a database of 40 thousand customers and we needed to communicate with them more proactively. We started to send educational emails to them and began posting relevant articles and videos on our website to educate and teach consumers about how wonderful our products are. To date, their response has been amazing. I am thrilled to be part of a company that can adapt fast, innovate constantly and is at the same time changing the lives of so many people.

