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OptiBiotix Health PLC
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OptiBiotix Health plc
("OptiBiotix" or the "Company")

Joint research agreement

Study to show how probiotic and prebiotics may improve sleep, stress, and anxiety

OptiBiotix Health plc (AIM: OPTI), a life sciences business developing compounds to tackle obesity, high cholesterol, diabetes and skincare, announces that its has reached an agreement with Fondazione Edmund Mach - Centro Ricerca e Innovazione ("FEM"), based in Trento, Italy, and the University of Southampton, to jointly fund and carry out a research project examining the role of its microbiome products (LP_{LDL}®, SlimBiome®/WellBiome®) to improve sleep, stress, and anxiety.

FEM is an academic research institute operating in the agri-food and environmental sectors. It is located in the Province of Trento in the Italian Dolomites and is the first "One Health" research centre in Italy. Within the Department of Food Quality and Nutrition at FEM, the Nutrition and Nutrigenomics Unit ("NNU") has internationally recognised expertise in probiotics, prebiotics, polyphenols and functional foods. The NNU mission is to measure how microbiomes along the food chain can be harnessed to improve food nutritional quality, food sustainability and improve human health. NNU has a special interest in fermented foods (especially fermented dairy products), functional ingredients, whole plant foods, their bioactive fractions (fibers, prebiotics and polyphenols) and probiotics.

This research project will be performed in the School of Human Development and Health ("HDH") in the Faculty of Medicine at the University of Southampton. HDH is internationally recognised for its multidisciplinary research in the area of nutrition and metabolism seeking to reduce the burden of non-communicable disease in both developed and developing countries. Research includes the application of systems approaches to understand the far-reaching effects of microbiome modulators on the biomolecular system of the host and their implications for health and disease.

The agreement funds a PhD studentship to explore the potential of prebiotics (e.g SlimBiome®/ WellBiome®) and probiotics (e.g LP_{LDL}®) for their ability to manage sleep, stress and anxiety. The agreement includes a double blind, placebo controlled, human study carried out during a period of stress induced sleep disruption.

The research follows on from a number of publications[1-5,7] indicating a relationship between the gastrointestinal microbiota, neurobiochemistry, and emotional behaviour. It builds upon findings showing that prebiotics improved anxiety and depression in participants consuming ≥ 5 g/day, and probiotic consumption improved psychological or biological measures of depression, anxiety, or stress in individuals predisposed to a mood disorder[6]. A study by Costabile *et al.* in 2020 showed ingestion of 7.5 g per day of SlimBiome® resulted in a statistically significant improvement in mood after 4 weeks (p = 0.0026).

[1]Swann J.R., Spitzer, S., Diaz Heijtz R. (2020) "Developmental signatures of microbiota-derived metabolites in the mouse brain". *Metabolites.* 10(5), 172.

[2]Caspani G. & Swann J.R. (2019) "Small talk: microbial metabolites involved in the signalling from microbiota to brain" *Current Opinion in Pharmacology*. 48: 99-106.

[3]Caspani G., Kennedy S., Foster J.A., Swann J.R. (2019) "Gut microbial metabolites in depression: understanding the biochemical mechanisms". *Microbial Cell.* 6(10): 454-481.

[4]Swann J.R., Garcia-Perez I., Braniste V., Wilson I.D., Sidaway J.E., Nicholson J.K., Pettersson S., Holmes E. (2017) "Application of ^{1}H NMR spectroscopy to the metabolic phenotyping of rodent brain extracts: a metabonomic study of gut microbial influence on host brain metabolism". *J. Pharm and Biomed Anal.* 143: 141-146.

[5]Farshim P., Walton G., Chakrabarti B., Givens I., Saddy D., Kitchen I., Bailey A., Swann J.R. (2016) "Maternal weaning modulates emotional behavior and regulates the gut-brain axis". *Nat Sci Rep.* 6: 21958.

[6]Holscher, H. & Tallor A. (2020) "A review of dietary and microbial connections to depression, anxiety, and stress". *Nutr Neurosci*. 23(3): 237-250.

[7] Patterson E, Ryan PM, Wiley N, Carafa I, Sherwin E, Moloney G, Franciosi E, Mandal R, Wishart DS, Tuohy K, Ross RP, Cryan JF, Dinan TG, Stanton C. Gamma-aminobutyric acid-producing lactobacilli positively affect metabolism and depressive-like behaviour in a mouse model of metabolic syndrome. Scientific Reports, 2019 Nov 8;9(1):16323. doi: 10.1038/s41598-019-51781-x.

Stephen OHara, CEO of OptiBiotix Health plc commented: "*OptiBiotix has developed products based on a scientific understanding of their mechanisms of action and human studies which demonstrate safety and efficacy. These studies examine a range of parameters beyond the main study endpoint and have indicated a potential for opportunities beyond cardiovascular health for LP_{LDL}®, weight management for SlimBiome, and gut health for WellBiome®. This agreement allows Optibiotix to explore the benefits of its existing products to help improve stress, anxiety and sleep disorders with world leading scientists and academic institutions. Sleep aids and stress management products are the fastest growing category within healthcare (Goldstein Market Intelligence, 2020). This is another step in extending the range of applications for OptiBiotix's scientifically and clinically proven products into large growing markets where there is an unmet clinical need.*"

Professor Jonathan Swann, University of Southampton commented: "*There is growing evidence for the bi-directional communication between the microbiota resident in the gut and biochemical processes and functions occurring in the brain. Such processes and functions can modulate cognition and emotional behaviour. This exciting project will apply high-resolution systems biology approaches to human studies*

exploring the potential for microbial modulators to improve stress, anxiety and sleep disorders. This will allow us to comprehensively characterise the impact of changes to the microbiome on its metabolic output and the biochemical flow to the human host. This information will help us to understand the biomolecular mechanisms underlying any potential changes in emotional behaviour. Such information will not only advance our knowledge in this field but will also assist in refining strategies to improve mental health."

Dr Keiran Tuohy, Fondazione Edmund Mach commented: "*Disrupted sleep and sleep apnea are recognised risk factors of poor metabolic health and cardiovascular risk and are closely related to stress. Recent research has identified an important role for the gut microbiota and specific probiotic strains in regulating not just circadian rhythms and the gut clock, but also in building resilience to emotional stress. Metabolites produced by gut bacteria from certain foods (e.g. prebiotic fibers or amino acids like glutamate or tryptophan) or through co-metabolism of bile acids produced in the liver, are thought to underpin communication along the gut:brain axis. Moreover, many of these same metabolites regulate inflammation and cellular metabolism, two processes intricately linked to cardiovascular risk. This project aims to screen a panel of probiotic strains and prebiotics for their ability to produce molecules linked to cell signalling processes in the gut and systemically related to regulation of circadian rhythm, brain function, stress, inflammation and energy metabolism."*

The Directors of the Company accept responsibility for the content of this announcement.

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About OptiBiotix - www.optibiotix.com
OptiBiotix Health plc (AIM: OPTI) is a biotechnology company formed in March 2012 which brings science and human studies to the development of compounds which modify the human microbiome - the collective genome of the microbes in the body - in order to prevent and manage human disease and promote wellness.

OptiBiotix has an extensive R&D programme working with leading academics in the development of microbial strains, compounds, and formulations which are used as active ingredients, supplements, and potentially drug biotherapeutic products. More than seventy international food and healthcare supplement companies have signed agreements with OptiBiotix to incorporate their human microbiome modulators into a wide range of supplements, fooid, dairy, and beverage products.

OptiBiotix is also developing its own range of consumer supplements and health products. The Company's current areas of focus include obesity, cardiovascular

health, and diabetes.

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