

Stock Data

Share Price:	58.0p
Market Cap:	£51.0m
Shares in issue:	87.9m

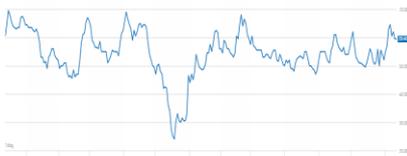
Company Profile

Sector:	Health Care
Ticker:	OPTI
Exchange:	AIM

Activities

OptiBiotix Health plc ('OptiBiotic', 'OPTI', the 'Group') was formed in March 2012 to develop compounds which modify the human microbiome - the collective genome of the microbes in the body - to prevent and manage human disease. The aim of OptiBiotix is to discover and develop microbial strains, compounds and formulations which modulate the human microbiome and can be used as food ingredients, supplements or active compounds for the prevention and management of human metabolic diseases.

1-year Share price performance



Source: [LSE](#)

Past performance is not an indication of future performance.

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OptiBiotix Health plc

OptiBiotix Health plc, the life sciences business developing compounds to tackle obesity, high cholesterol, diabetes and cardiovascular health, is now in a pivotal position. Having delivered a five-fold increase in H1 2020 revenues on the comparable period, the Group's scalable business model is positioned to capture long-term growth from a portfolio of highly protected and proven products through licensing, royalties and distribution agreements with multiple international partners. With rising incidence of lifestyle-related conditions and expanding geriatric populations seen as the principal demand drivers for non-toxic human microbiome therapeutics as an alternative route for tackling such endemic healthcare challenges, one research institute projects a sector CAGR of 22.6% between 2017 to 2025 in a marketplace that, although presently dominated by North America continues to expand rapidly in both Europe and Asia. Despite the uncertainty the Pandemic has injected into the global economic environment, OptiBiotix is expected to capture this market opportunity through continued expansion of its range of applications, products and territories.

Strategy – Limiting commercial risk, building product credibility

OptiBiotix products address giant global markets with significant unmet need across multiple channels (including supplement, dairy, food, pharma and biopharma). Its highly scalable business model is designed to limit investor development and regulatory risk through the signing of agreements with a large number of partners in different global territories across all parts of the value chain (including manufacturing, formulation, quality control and distribution). Core technologies and know-how are highly protected, while experienced industry leaders with track records for building revenues head the Group's different divisions, each with a directive to drive sales while moving their units to sustainable, independent profitability.

International footprint already in place

The Group's first-generation products now sell into over 120 countries around the world, creating global brand awareness in the process. This has been achieved through multiple agreements with large retail and pharmaceutical partners including [Alfasigma](#), [Agropur](#), [Costco](#), [Holland & Barret](#), [Optipharm](#), [Walmart](#) etc., taking products containing [SlimBiome](#)[®], [LPLDL](#)[®], [OptiBiome](#)[®], and more recently [WellBiome](#)[®], to the mass consumer. As a result, OptiBiotix is increasingly being [identified as a key, international player in the microbiome space](#).

Next generation products to deliver increased differentiation

Although distribution agreements with major international retailers can be seen to squeeze overall margins, they nevertheless afford a tick of credibility to OptiBiotix product range, thereby sustaining interest in adjacent markets. This is something that is likely to be further evidenced in coming months. Significantly in this respect, commercialisation of the Group's next generation products, including [microbiome modulators](#), [biotherapeutics](#), and the growing [SweetBiotix](#)[®] family, is now underway. Of note also is the increasing number of pharmaceutical companies, such as [Alphasigma](#) and [Actial Farmaceutica](#), that are commercialising LPLDL[®] products into the high value GP, hospital, and pharmacy markets. The first half of the current year also saw the completion of a second successful human study by ProBiotix Health, OptiBiotix's wholly-owned subsidiary, this time in partnership with [Nutrilinea Srl](#), which demonstrated that a new food supplement formulation containing LPLDL[®] can both reduce high blood pressure (hypertension) and cholesterol, while remaining safe and well tolerated.

OptiBiotix's core product offering

2020 to date has seen OptiBiotix sign 17 new commercial agreements: 12 for SlimBiome® and 5 for LPLDL®. A significant milestone was passed on [15 September 2020](#) with the signing of a US partner for large scale manufacture and commercialisation of a number of SweetBiotix® products; on [22 September 2020](#) a non-exclusive license was also agreed with [HiLife Vitamins & Herbs Co Inc.](#), conferring rights to commercialise OptiBiotix's proprietary weight management product, [SlimBiome® Medical](#), in the USA. Any subsequent exclusivity agreed will be linked to minimum order quantities.

LPLDL®

Lactobacillus plantarum LPLDL® is considered a next-generation probiotic that aids elements of cardiovascular and wellbeing. Demonstrating an exceptional capacity to modulate the metabolism of bile acids, its activity is important to bacterial survival in the intestine's hostile environment and aids conditions such as high blood pressure and high cholesterol, as well as physiological processes including vitamin metabolism, glucose regulation and liver function. It has been shown in randomised, placebo-controlled human intervention studies to deliver tangible health benefits, reducing cardiovascular risk factors and supporting overall heart wellness, including the lowering of total cholesterol (by up to 36.7%) and systolic blood pressure (by 5.1%), while remaining safe and well tolerated.

The Group now has partners commercialising LPLDL® in over 60 countries, including the world's largest probiotic market (USA: [Seed Health](#)) and second largest (Italy: AlfaSigma). The next stage of its strategy is to expand sales with existing partners and extend territories/applications, while continuing to sign up new partners. In addition, it is renegotiating contracts as volumes increase to reduce the cost of goods. The renegotiation of OptiBiotix's contract with Sacco Srl, announced on [11 March 2020](#), from a profit sharing to a manufacture supply agreement should improve Group margins, the results of which should be seen in H2 2020. Recently secured [GRAS](#) and [GMP](#) designations will also increase the market appeal of the product to pharmaceutical partners either used on its own, or as combination treatment to help lower the dose and potential side effects of statins. This further extends OptiBiotix's opportunity outside the traditional supplement market into broader therapeutic opportunities, which are also being explored more actively in H2 2020.

Total sales of LPLDL® as an ingredient or final product [grew by 477% in H1 2020](#) compared to the same period last year.

SlimBiome®

SlimBiome® is formulated to reduce cravings for savoury and sweet foods, has a positive impact on gut microbiome and mediates significant weight loss in overweight to obese women as part of a calorie-controlled diet. Stimulating the growth of health positive bacteria in the digestive tract to affect regulation of appetite, its blend of [prebiotics](#) and dietary fibres helps to create a longer-lasting feeling of fullness, while the trace mineral content enhances the body's use of insulin, helping to metabolise carbohydrate and fat. As such, it satisfies market demand for a sustainable, healthy and stress-free slimming aid by replacing harsh self-discipline as the key to weight loss with tasty, science-backed applications.

Sales of SlimBiome®, as an ingredient or final product, [grew by 1,309% in H1 2020](#), compared to the same period last year. This was largely driven by partners in the UK, Australia and the USA either launching retail products or building stock levels for the launches. Of importance is the extension of SlimBiome® into everyday foods like muesli and porridge and the development of healthy snacks like fruit and fibre gummies under the SnackSmart® brand. The launch of WellBiome® at the end of H1 2020 reflects growing interest from partners in a science backed Health and Wellbeing microbiome product which taps into a global trend for Health & Wellness, a [market estimated to be worth](#) US\$4.2 trillion in 2019 with the digestive health segment accounting for US\$60 billion.

SweetBiotix®

SweetBiotix®'s concept uses new science, new manufacturing processes, and is a step change from existing products on the market or understood to be under development. Around half a dozen types of SweetBiotix® products are already available with a couple more now in development. The aim is to have a broad range suitable for different application areas which meet the needs of multiple partners on areas as diverse as dairy, cereals and hot & cold beverages. The agreement signed on 15 September 2020 with a US partner for large scale manufacture and commercialisation of a number of SweetBiotix® products represents an important milestone. It grants an exclusive worldwide license in return for the partner bearing the substantive manufacturing, marketing and all related future commercialisation costs. OptiBiotix will receive a modest six-figure payment from the company on signing and at 12 monthly intervals until product launch. Additional similar payments will be due on product launch plus royalties on all future product sales. Enhanced royalty payments will be made to OptiBiotix on sale of SweetBiotix® products by the Company to 11 application/innovation partners with whom OptiBiotix has been in long term discussions regarding exploring the use of SweetBiotix® products in dairy, cereal and beverage applications.

No universally agreed regulatory framework

The regulation of probiotics, which are responsible for modulating the host intestinal microbiota, differs between countries: there is no universally agreed framework. In the European Union, for example, probiotics and food supplements are regulated under the Food Products Directive and Regulation (regulation 178/2002/EC; directive 2000/13/EU). All health claims for probiotics have to be authorised by the EFSA. The EFSA has issued a list of microbial cultures that have a [Qualified Presumption of Safety](#), meaning that they do not require safety assessments. The EFSA is also responsible for assessing health claims made for probiotic products. In the United States, most probiotic products are classified as foods or dietary supplements; dietary supplements are required to comply with Good Manufacturing Practice ('GMP') guidelines, but these do not [extend to testing quality or efficacy](#). As in Europe, dietary supplements cannot make disease-specific claims, but in the United States they are allowed to make structural or functional claims such as 'supports healthy digestion', accompanied by an FDA-mandated disclaimer. Claims must be truthful, not misleading, and [substantiated by scientific evidence](#). There is also a category of probiotics which are formulated to be consumed or administered enterally under the supervision of a physician and which are intended for the dietary management of a specific disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation. These formulations fall in the category of 'medical foods' in the United States. Medical foods are not drugs and so are not subject to any regulatory requirements that specifically apply to pharmaceuticals. However, a medical food that bears a false or misleading claim would be considered misbranded under section 403(a)(1) of the [Federal Food, Drug, and Cosmetic Act](#).

The expanding use of probiotics around the world is likely to increase pressure for adoption of a more universally agreed regulatory framework in coming years. While heightening product credibility as a solution to multiple ailments, this would also work to OptiBiotix's benefit through the prospective removal of poor quality, commoditised, sometimes mis-labelled products that still routinely find their way onto western shelves, having originated from various low-cost territories and primarily contribute to both confuse the buyer and undermine viability of the therapeutic opportunity.

Erecting barriers in a lightly regulated marketplace

Differentiating itself from other market providers, OptiBiotix's product credibility has been enhanced through heavy investment in science, human studies and regulatory approvals (GRAS, GMP), supported also by a comprehensive suite of 70 patents, 19 patent families and 68+ trademarks in order to establish a recognised position in the microbiome field. This has been further reinforced through independent peer reviewed publications, along with [Medical Device](#) launches (e.g SlimBiome Medical) and pharmaceutical products (e.g [Ezimega 3, DS-01™](#)).

[Prebiotic agents have been defined](#) as food for microbiota that is selectively fermented, resulting in specific changes in the composition and/or activity of the gastrointestinal microbiota, thus conferring benefits upon host health. In this respect, the regulatory aspects for such products are considered by different national agencies (such as the [EFSA](#) or the [FDA](#)), to cover areas including efficacy, safety, quality control of manufacturing, along with any specific claims of therapeutic outcomes that may be derived from application of individual products. OptiBiotix's existing preparations do not make disease-specific claims and are therefore classified as food supplements or dietary supplements. In some cases, however, when the clinical data are convincing for a certain formulation, a product can be classified as a medical food intended for the dietary management of a specific disease (ie, pouchitis). Both of these categories are regulated much less stringently than pharmaceuticals, through which the Group has delivered a first generation of products with low development risk in order to establish its product position and test its innovative business model in the international markets.

Sharply rising consumer awareness of the health and lifestyle benefits that can accrue from management of the human microbiome, combined with reputation built on international branding, however, now provide it with opportunity to capture a significant share of this rapidly expanding marketplace that has been forecast to reach a global value of [US\\$3.97 billion by 2026](#) according to Polaris Market Research. While seeking to grow profitability in each division by scaling sales, improving purchasing power and focusing on higher margin areas, OptiBiotix is now commencing the commercialisation stage of its next generation of products centred around microbiome modulators, drug biotherapeutics and its expanding SweetBiotix® family.

Pharmabiotics

Still rather new in terms of clinical application, OptiBiotix is helping to lead the pharmaceutical development industry by working with selected partners in the development and prospective commercialisation of prescriptive products.

The term '[pharmabiotic](#)' has been coined to encompass therapeutic formulations with potential health benefit that can be mined from microbiota, microbiota–host, or microbiota–dietary interactions in the gut. It includes not just live organisms but dead or altered organisms as well as bacterial products or metabolites. In 2012, the FDA created a new category, 'live biotherapeutic product' ('LBP') for microbiome drug approvals. No LBP products have been approved as yet, with developers said to still be inventing novel identity, potency and purity assays for these products, as well as new markers of – and even definitions for – drug pharmacokinetics and pharmacodynamics. In August 2020, however, [Seres Therapeutics](#)' gut microbiota capsule SER-109 met its primary end point in a phase III trial in recurrent Clostridium Difficile Infection ('CDI'). Other relatively advanced developers of microbiome-based drugs include [Finch Therapeutics](#), [Rebiotix](#), [NuBiyota](#), [Seed Health](#) and [Vedanta Biosciences](#), each of which has one or more indications currently in clinical trials.

Using OptiBiotix's Lactobacillus plantarum LPLDL[®], [Seed Health Inc.](#), the US microbial sciences company, confirmed on [2 October 2020](#) it had received FDA authorisation for an Investigational New Drug ('IND') application for DS-01™, a broad spectrum multi-species, multi-strain probiotic. Regulatory acceptance now enables it to enter a Phase II randomised, triple-blind, and placebo-controlled clinical trial to investigate the role of the gut microbiome in patients with Irritable Bowel Syndrome ('IBS') and the wider impact of DS-01™ on intestinal microbial communities. Based on licensing and royalty agreements for use of its proprietary products, such developments offer low-risk potential to boost the Group's gross margins and longer-term visibility, while also reinforcing its reputation in this specialist area. OptiBiotix sees opportunity for further similar development partnerships in the future.

Results for the six months to end-June 2020

[Results for six months ended June 2020](#) have been compared with the six months ended 31 May 2019, due to the Group's change in its financial year-end from November to December in 2019.

Revenue for the period increased five-fold to £744,821 (2019: £148,818). This was achieved despite difficult trading conditions in a number of territories, which may have impacted on sales in retail outlets and reduced visits and sale opportunities from partner representatives visiting hospitals, GPs, and pharmacies due to COVID-19 restrictions. In contrast to 2019, where the majority of this income was generated from LPLDL[®], in 2020 the functional fibres division (SlimBiome[®], OptiBiome[®] and WellBiome[®]) made a roughly equal contribution of £342,734 compared with £341,858. The Group's online store also generated £60,229 revenue. As in previous years, there was no substantive contribution from license or royalty payments which tend to be received in the second half of the year and tend to influence gross margin. The renegotiation of a contract with Sacco Srl is also expected to boost margins in H2 2020. Administrative expenses for the period were £896,268 (2019: £1,025,050) with £162,840 non-cash expenses representing depreciation, amortisation and share based payment charges (2019: £157,112).

As at 30 June 2020, the Group had a £1.47m cash balance. Adding R&D tax credits claimed and recoverable VAT repayments, the balance rises to £1.68m. During the period, OptiBiotix received £746,751 of investment income from the disposal of shares held in [SkinBioTherapeutics plc](#) (AIM: SBTX). As of 1 June 2020, OptiBiotix held 29.8% of SkinBioTherapeutics plc which, at a [share price of 18.5p/share](#) (10:00hrs on 13 October 2020) equates to a value of £7.15m. OptiBiotix's Chairman, Neil Davidson and the CEO/founder, Stephen O'Hara, noted in their interim statement that the Board continues to explore potential for a dual international listing in the USA or other international markets.

Positioned to capture years of strong growth

The study of the human microbiome is presently one of the hottest areas of biology and biomedicine. Its application to prevent, treat or mediate various lifestyle-related conditions, with potential to substantially improve quality of life, is now attracting attention worldwide. OptiBiotix has adopted different strategies to capture this opportunity through a sophisticated, low-risk business model. It has already laid foundations which offer potential to sustain strong medium-to-longer-term growth in what is a [highly fragmented global market](#) that is projected to expand quite dramatically over the coming decade amid global escalation and rising consumer awareness. The commercialisation of OptiBiotix's next generation of products, should present a simpler and speedier process to 'bolt-on' to the existing network. While complementing the existing offering, focus is increasingly on higher value-added and partnerships, with potential to broaden its portfolio further into areas that include hospitals, GP surgeries and pharmabiotic markets. OptiBiotix is also seen as a net beneficiary of any future regulatory tightening, which might be expected to squeeze out many of the smaller, bit-part and/or non-compliant sector participants, resulting both in a phase of consolidation and increased recognition of the sub-sector's contribution to humankind's wellbeing.

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