October 2021

Newsletter

Welcome to the Sativa Wellness Group newsletter. Produced to offer you a snapshot on the latest news from the Group. We welcome feedback and if you would like further information on any of the articles, please contact us on enquiries@sativawellnessgroup.com.

SATIVA WELLNESS GROUP™

CBD

Introduced a membership model to build predictable revenues.

Secured distribution agreement with partners in Germany.

Introduced 30ml bottles and offered a price guarantee.

Clinics

Significantly increased the footprint within the UK.

Over 70 clinics to date.

Expansion of the product range incorporating Influenza A&B and RSV.

PHYTOVISTA LABORATORIES

Concluded the ISO17025 accreditation.

Working with the Polish Laboratory to expand cannabinoid testing in Europe.

Marc Howells

Sativa Wellness Group have appointed Marc Howells as the new CEO to deliver the company's strategy. Marc has a track record of over 36 years in the finance sector with in-depth experience expanding integrations, mergers and acquistion, restructuring and scaling start-ups. "I am excited to deliver our huge ambitions in developing the 3 business units to become an internationally recognised wellness company". He had built up geographical and cultural expertise across China, Europe, ISA and South Africa.

Financial highlights

Our Q1 produced the best quarterly turnover to date for any quarter since Sativa Wellness and its predecessor Sativa Group Plc started in 2018 at £1.37m.

Q2 produced even stronger revenue with the first quarterly profit since inception.

Message from Geremy

The last six months have produced strong financial and operational results. With our new CEO, Marc Howells, we have developed our roadmap through three distinctve business units- Goodbody CBD, Goodbody Clinics and PhytoVista Laboratories.

We have a clear and strong strategy to deliver our vision to become one of the best known wellness brands.

Our vision for Goodbody

We are pleased to announce that a full membership scheme and product range to include larger 30ml CBD oils has been launched.

For members, 20% CBD Oil in 30ml bottles is 20% cheaper and 20% stronger than the cheapest CBD on the market. Members will receive major discounts to competitor offerings without any compromise on quality.

Our Goodbody brand also guarantees the Best Quality & Best Price on the market. Goodbody guarantees consumers their money back if, a CBD oil, of the same quality and strength as Goodbody CBD, is found for a cheaper price.

Olimax – Our CBD Extractions plant in Poland

We are pleased to announce that Sativa's polish extraction facility has secured accreditation of its Hazard Analysis and Critical Control Point (HACCP) system from the global quality and certification company LL-C Group, and confirmation that its operations meet the requirements for Goods Manufacturing Process (GMP) and Good Hygiene Practice (GHP) standards for food manufacturing.

The team in Poland are also developing new products for the group...watch this space!

Olimax Visit

In September Marc Howells (CEO) and Anne Tew (CFO) visited the Polish management team in Olimax, Poland.

Over a couple of days, they agreed the business plan and future direction of the Polish plant with the Polish management team, who are very excited about the future. Olimax as Sativa Wellness Poland will start to produce Goodbody products for the European market and will play a key role in future product development.

Lexamed

German Distribution Agreement

We have signed a distribution agreement with German partners Lexamed GMBH ("Lexamed"). This exclusive agreement will allow both parties to work together to build the Goodbody CBD brand within Germany with plans to expand this to other European countries in the future.

The German market has a strong CBD market, and this is a great opportunity for both companies. The existing Goodbody range will be offered through a number of channels in Germany and the companies will also work together to develop new products for the European market in conjunction with Sativa Wellness's Polish extraction and manufacturing facility.

Online GP service and our 70th clinic

At Sativa, we now offer customers a private video call medical consultation with a registered GP to discuss the results of your chosen blood wellness test.

We have collaborated with The GP Service.co.uk with a dedicated booking system for customers. The GP service offers a convenient, discrete, and secure service to help diagnose and treat common conditions. All the doctors are UK based and registered with the General Medical Council.

Our customers have a choice to pay an additional fee to include the follow up appointment as part of their blood test. They simply complete a short registration and enter their unique voucher code.

This information can be shared with their GP upon their agreement.

Over the last 6 months we have grown our number of clinics to over 70 nationwide. Our strategy is to provide complete customer solutions within the wellness sector through the expansion of our distribution network and portfolio of products serviced direct and via trusted partners.

We currently offer 16 blood tests from cholesterol to pre-diabetes HbA1C – some of which require a phlebotomist drawing blood in-clinic and other tests as home kits.

This month we are also providing clinics an CBD on-boarding package. This package allows the clinic to trial the CBD range and have all the necessary promotional collateral to support that trial.

16
blood tests

70
clinics nationwide

PhytoVista Laboratory

We are pleased to announce that the Phytovista Laboratories having achieved ISO17025 accreditation will be extending this standard to the Olimax laboratory staff that will be joining the Phytovista team to provide more services within Europe.

Accreditation to ISO/IEC 17025 plays an important role in supporting the provision of accurate and reliable results from laboratory testing, calibration, sampling and measurement services across many sectors.

The technical competence of a laboratory depends on several factors including:

- The qualifications, training and experience of the staff
- The right equipment – properly calibrated and maintained
- Adequate quality assurance procedures
- Proper sampling practices
- Appropriate testing procedures
- Valid test methods
- Traceability of measurements to international standards
- Accurate recording and reporting procedures
- Suitable testing facilities

UKAS accredited means the evaluator can demonstrate to its customer that it has been successful at meeting the requirements of international accreditation standards. Usually, the reason for getting something independently evaluated is to confirm it meets specific requirements to reduce risks. Obvious examples are company reputation or to meet legal or customer requirements.

Anything or anyone can be evaluated – products, equipment, people, management systems or organisations. UKAS is appointed as the sole national accreditation body for the United Kingdom under S.I No 3155/2009 and operates under a Memorandum of Understanding (MoU) with The Department for Business, Energy and Industrial Strategy (BEIS). An independent evaluator accredited by UKAS also means that evaluators for testing and calibration laboratories, inspection and certification bodies have been assessed against internationally recognised standards to demonstrate their competence, impartiality and performance capability.

Customers that use laboratory services will generally require a laboratory that can provide accredited results to satisfy their internal quality requirements as part of their approved supplier checks (such as those defined in manufacturing ISO standards). The value of accredited results is higher than that of unaccredited results in ensuring that robust and defensible data is used to ensure that products meet their specifications.

Other news for PhytoVista – we have launched a new UK website with European versions to be added at a later stage.

Novel Foods Update

CBD extract and isolate products were confirmed as novel food products in January 2019. Under the novel food regulations, foods or food ingredients which do not have a history of consumption before May 1997 should be evaluated and authorised through the Novel Foods submission process before they can be placed on the market.

This process ensures novel food products meet legal standards, including on safety and content. It will also help consolidate the market.

To bring the current market into compliance, the FSA exceptionally asked the industry to submit retrospective applications, for CBD products which were on sale on 13 February 2020. The products linked to the applications which are making initial progress through the novel foods' authorisation are allowed to stay on the market until a decision on their authorisation has been made.

In this respect, we submitted our evidence for the products that we sold prior to 13 February 2020. We have completed this stage and unlike most CBD companies we have submitted our own CBD formulations rather than 3rd party formulations.

There are a number of stages in order to achieve full accreditation:

Stage One Validation

Validation is the first stage of the novel foods process. Validation does not mean that these products are authorised novel foods and confirmed as safe for consumption, it means that they are allowed to stay on the market until a decision on their authorisation has been made. Only those businesses that have provided FSA with adequate information on compositional data, stability studies, toxicology and Geno toxicology studies, bioavailability, can progress their application.

Most applications, including ours, have not been validated yet due to outstanding data on safety studies. Our applications are progressing well towards providing this information, with evidence of plans to complete the risk assessment process to an acceptable quality and with a clear agreed deadline for submission for validation.

Products linked to these applications will be included in the 'on hold' category, meaning that the rest of the application was considered suitable for validation.

Publication of the public list to detail the products that have submitted safety evidence such as stability and toxicology reports for the Novel Foods process. This was due to be made public by the end of August. The FSA have been inundated and have just updated their status mid-September to say that they cannot give a definite date as to when this will happen. The implication is that many retailers are waiting on this list before they agree partnerships with any CBD brands. The original date given by the FSA was the end of August but, like all brands, we are waiting on that update. Currently they do state that CBD products are allowed to stay on the market in England and Wales until that decision on their authorisation has been made.

Also, many CBD brands who have not submitted are 'selling off stock' or selling up.

Stage Two Risk assessment and Risk mitigation

Based on the evidence provided, the Advisory Committee on Novel Foods and Processes (ACNFP) which is an independent advisory committee and has been in existence since the Novel Food Regulation, will conduct the risk assessment. They will consider possible risk management options and make a recommendation to ministers. The ministers will then decide whether the product should be authorised for use in Great Britain. There will be an opportunity to comment on the application by taking part in a consultation during the risk analysis process and before the final recommendation is made. Assuming a decision is taken to support an authorisation, the legislation will be updated to reflect the change.

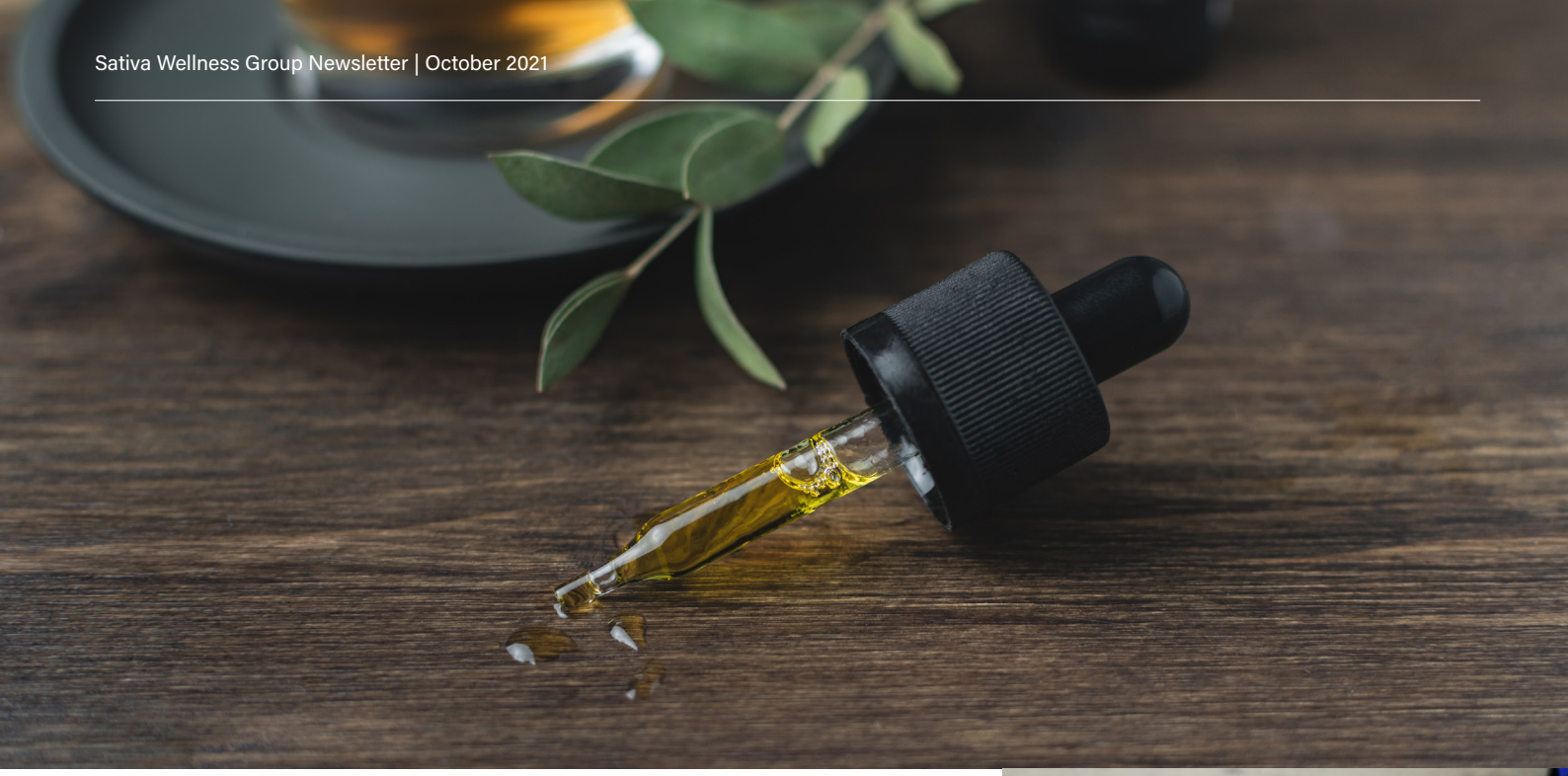
Stage Three Authorisation

The full novel foods authorisation process is expected to take at least a year before a final decision is made.

Latest news from the FSA

An internal scientific panel met on 21st September 2021 to make recommendations on whether some applications are suitable to be added to the "On hold" list. The panel will be looking at the scientific quality of the proposed toxicology studies.

The FSA is not committing to any timescales because there are several factors to consider in planning next steps and the volume of applications has been so high.



FSA Novel Food Application

The EFSA have confirmed that it had been in regular contact with other agencies, such as the UK FSA and the US Food and Drug Administration (FDA) – though less since the start of the COVID-19 pandemic – on relative stances on CBD food products. However, it would not treat a CBD product that had received approval from another food safety authority any differently than any other novel food application.

In other words, products approved by other authorities will not be fast-tracked and must go through the EC's normal application process.

The EFSA has established an acute reference dose for THC of 1 µg per kg of body weight, and the EC reaffirmed that any product that delivered a higher dosage would not be approved by the EFSA.

To apply for European Novel food application, we need to have completed all safety studies, including stability studies, toxicology and Geno-toxicology studies.

We are aiming for the first quarter of the next year to have completed all safety studies to be able to apply for EU authorisation.

Sativa Sponsorship of British F4 Racing Driver

Over the years Sativa has built a relationship through sponsoring racing driver James Hedley. A rising star as the Ginetta Junior Champion in 2019, James has switched to F4 Carlin racing and is currently trialing in F3.

Make sure that you sign up to our social media channels for the Sativa Group and our brands

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