OXFORD CANNABINOID TECH. (LON:OCTP)

January 17, 2024

Pharmaceuticals, Biotechnology & Life Sciences

52-WEEK HIGH	**£0.69**
52-WEEK LOW	**£0.66**
PRICE	**£0.70**
MARKET CAP MLN	£6.63

Share Price

Major Shareholders

Kingsley Capital Partners 20.76%	
Imperial Brands Ventures 10.87%	
Kee Cheol Noh 5.29%	
(% fully diluted)	
Shares in issue	960,415,644
Avg Three-month trading volume	4,591,256
Primary index	MAIN
Next Key Announcement	FY24 results summer 2024 MAD trial starts mid 2024

Company Information

Address: Prama House, Oxford OX2 7HT
Website: www.oxcantech.com

Analyst Details

John Savin PhD
JSavin@proactiveinvestors.com

Oxford Cannabinoid Technologies: Clinical outlook for 2024

Phase I Single dose competed with 2024 next-stage plans

Oxford Cannabinoid Technologies (OCT), a UK-based therapeutics company, specialises in developing proprietary pharmaceuticals based on synthetic or sophisticated derivative cannabinoids. The focus is on clinical studies in pain relief plus, in research, on new cancer adjuvant therapies.

In autumn 2023, OCT completed dosing in its first clinical study: a single ascending dose (SAD) 32-participant safety trial on OCT461201 ("201"). The product, a synthetic molecule targetting the Cannabinoid 2 receptor, (CB2) showed no safety issues or adverse events at all doses used. This is an excellent start to the clinical stages of development.

Funding permitting, we expect the continuation of a multiple ascending dose (MAD) study in healthy participants to start around mid-2024. We understand that this will evaluate two midrange doses over 14 days. This will provide critical information on the longer-term dosing and accumulation behaviour of 201. We expect this MAD study to be completed in early autumn with data around calendar year-end 2024. It will open the way to a potential FDA IND submission which would allow US clinical studies possibly from 2025. The proposed Phase 2 indication is established chemotherapy-induced peripheral neuropathy (CIPN): nerve damage and limb pain caused by cancer chemotherapy. OCT estimates the CIPN market could be worth US$1.17 billion by 2028.

A further major market in pain control in Irritable Bowel Syndrome is being evaluated. This will require separate Phase 2 studies.

OCT has three other projects: OCT130401 ("401") is aimed at the rapid relief of trigeminal neuralgia (sudden, severe facial nerve pain). It is a combination of two cannabinoids to be given by a metered inhaler and could enter Phase 1 in 2024. Programme 3 is a pain project derived from OCT's combined proprietary and in-licensed library of 475 molecules. Program 4 is in earlier-stage research. It aims to boost the immune response to solid tumours using cannabinoid derivatives from OCT's molecular library. An oral immuno-oncology agent could have a high commercial potential.

Finances and investment conclusion

FY23 results to 30 April 2023 were released in August 2023 and showed cash

of £2.3mln. Management expects that available cash will be fully utilised by April 2024. A tax credit of $0.7m was received in August CY23 and a further £1.8mln tax credit is due for payment in 2024. Operational spending in FY23 was £7mln (£4.3 mln R&D; £2.7mln admin), up from £5.4mln in FY22. The loss was offset by a £1.1mln tax credit. OCT plans to focus its resources on 201.

The market capitalisation of about £6.6mln reflects the current market for earlier-stage biotechnology stocks and the need for further funding. In our view, OCT remains an interesting opportunity since the major lead project, 201 has successfully completed the initial stage of its first human trial. However, further funding is needed imminently.

Year end Apr 30	2022	2023
Operating profit (£,000s)	(5,503)	(5,945)
Net Cash	9,266.0	2,297.0

Clarissa Sowemimo-Coker (CEO) joined the group's executive team in December 2018 as general counsel and company secretary. She was appointed to the board in February 2021 as chief operating officer. In December 2022 Clarissa was appointed as chief executive on an interim basis, and confirmerd as permanent CEO in April 2023. She was formerly a solicitor and commercial consultant to companies in the retail, telecoms and pharmaceutical sectors. She is also a management coach. Clarissa holds a BA in philosophy and literature from Warwick University and PGDL and LPC from BPP Law School in London.

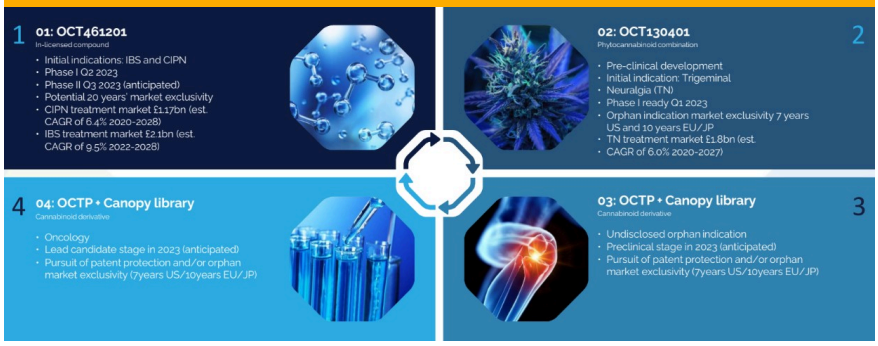
Julie Pomeroy (non-exec chair) is an experienced finance director. She has an honours degree in physics from Birmingham University, is a chartered accountant and chartered director. She also holds tax and treasury qualifications.

Paul Smalley (finance director) joined OCT in October 2022 from Panthera Biopartners Ltd, a clinical trials management company, where he was the finance director and company secretary. He is a CIMA qualified accountant with over 25 years' experience. He has worked in a variety of organisations, from SMEs to quoted companies. Paul holds a BA in Accounting & Finance from Lancaster University and is also a chartered global management accountant.

Pipeline

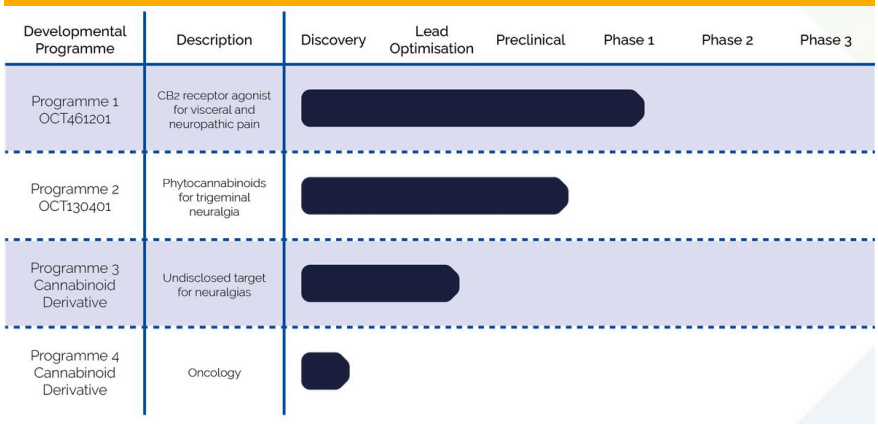
OCT has a pipeline of '201', plus three projects (Exhibit 1). OCT130401 is a synthetic cannabis mixture of THC and CBD delivered by a metered dose inhaler. It is aimed at rapid pain relief of trigeminal neuralgia (TN): acute onset facial pain. Programmes 3 and 4 are in earlier research stages. Programme 3 targets neuralgia, and any stabbing nerve pain; Programme 4 is an immuno-oncology project in the research phase. Exhibit 2 shows the development stages

Exhibit 1 - OCT's four programmes



Source: OCT Aug 2023 Presentation

Exhibit 2 - OCT 2024 pipeline



Source: OCT Website (Jan 2024)

201 phase I design: SAD done; MAD next stage

OCT's lead drug 201, Programme 1, is a first-in-class cannabinoid receptor 2 (CB2) selective agonist. The first stage was completed in 2023 using a SAD format with 4 cohorts of 8 volunteers (32 people) to assess dose and safety. This is a solid basis for further development. However, It does not give any efficacy information. The trial (ISRCTN39003837) is registered on the ISRCTN database; this is not helpful as most details are redacted. The SAD study had a starting dose of 10mg and could have used up to 470 mg - the level reached has not been disclosed. The next step will be a MAD study. This could start, funding allowing, in mid-CY24 and have data by late CY24 or early CY25. Two dose arms (low and high) are likely with a short pause to evaluate safety. We expect doses of between 50mg and 150mg twice per day for 14 days will be selected.

Potential phase II

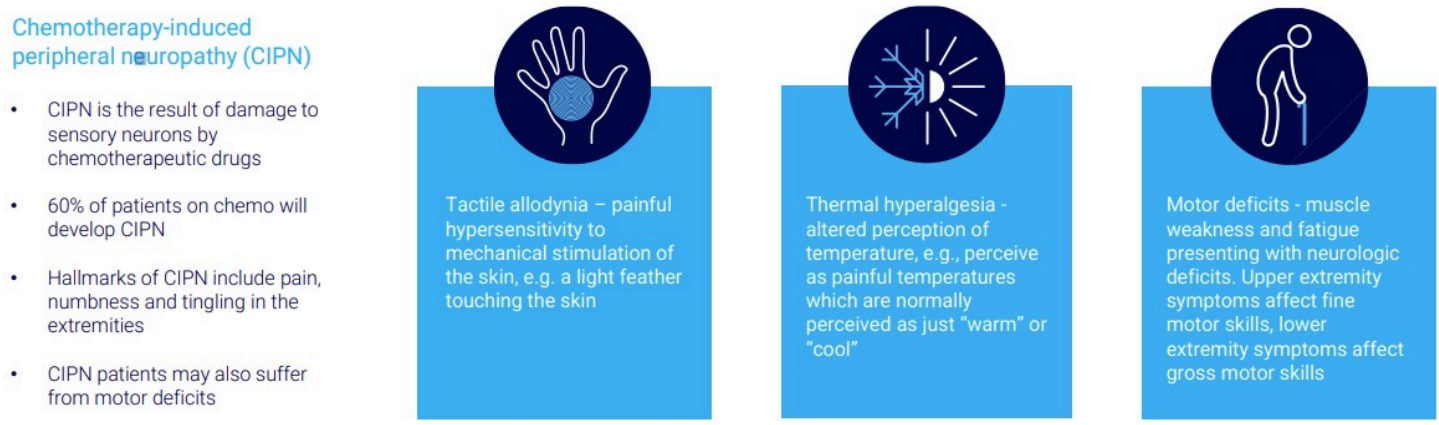
From 2025, a Phase 2 in patients with established CIPN could be run which could give some signs of efficacy; this could lead to partnering discussions. The mechanism is not fully understood as CB2 has received less study than the CB1 (the target of psychoactive THC).

CIPN need and market

As shown in Exhibit 3, CIPN is caused by cancer chemotherapy damaging the nerves. A paper in 2022 (Lin *et al*) based on a sophisticated animal model supports the hypothesis in addition to OCT's own internal research. A 2021 paper by Yang *et al* (2021) reviewed the area. The general area of CB2 receptors was the subject of a special journal issue in 2022 (Smoum *et al* 2022)

Initially, 201 will be trialled in Phase 2 in patients who have completed a course of chemotherapy and developed CIPN which did not resolve after several months of recovery. Established CIPN provides a clearer baseline from which to assess efficacy in a patient group with a clear medical need. OCT puts this market at about $1.17bln. With good Phase 2 data, 201 could be an excellent candidate for partnering.

Exhibit 3 - CIPN - nerve damage due to cancer chemotherapy



Source: OCT

External CB2 developments

A Phase 2b trial of a promising CB2 agonist, olorinab (Pfizer) did not meet its endpoint in a study of irritable bowel syndrome (Chang *et al* 2023) emphasising that careful choice of indication is essential. Other companies that have targeted CB2 in clinical trials in the last five years include Corbus and Centrexion.

Programme 2: 401

The company's second programme OCT130401 ("401") is a combination of cannabis molecules: synthetic THC (dronabinol (DBN)) and CBD a 1:1 ratio. The mixture is delivered to the deep lung using an off-the-shelf, metered-dose, pressurized inhaler (Exhibit 4) for fast absorption through the lung.OCT envisages that 401 can provide quick pain relief from the sudden onset of stabbing severe facial pain in trigeminal neuralgia (TN), Exhibit 5.

Exhibit 4 - 401 inhaler



Source: OCT presentation

Exhibit 5 - TN clinical facts

Trigeminal neuralgia
TN, i.e., tic douloureux, described as the most excruciating pain known to humanity. Pain is SUDDEN, intense, stabbing, throbbing, electric shock-like.

Causes
TN is normally caused by irritation of the trigeminal nerve (e.g., compression by artery/vein or tumour).

The nerve keeps misfiring WITH NO TRIGGERS. Hypertension, MS (demyelination), family genetic also are risk factor.

Impact on Population
TN is on the rise : ~15,000/20,000 new cases in the US each year In 2021, an estimate 77,000 suffered from TN It is most common on >50yo women. It is an orphan disorder.

Source: OCT Aug 2023

Preclinical work has now been completed and the project put on hold to improve cash flow and focus on 201. The 401 project can be fast-tracked once funding is available. Phase 1 is planned to run in Australia probably due to the more sympathetic approach of the

Therapeutic Goods Authority (the regulator) towards cannabinoid therapeutics. This would be an orphan drug market and could be worth, in OCT's estimate, about £1.8 billion.

Programes 3 and 4

OCT is expanding and diversifying its cannabinoid pipeline with programmes 3 & 4 utilising its extensive cannabinoid library. These candidates come from OCT's cannabinoid library of 475 derivatives (Exhibit 6). The library includes 335 derivatives that the company has exclusive rights to use across THC, CBD and CBG derivatives, as well as 140 cannabinoid molecules through its collaboration with Canopy Growth Corporation.

Programmes 3 and 4 cannabinoid derivatives will be paused once at pre-clinical and lead stages till funding allows.

Exhibit 6 - OCT pipeline mix



Source: OCT Investor Presentation

Programme 3 - on clinical entry pathway

Programme 3 is a novel analgesic for a rare pain condition. The candidate is a dual agonist of CB1 and CB2 receptors, which are part of the endocannabinoid system (ECS) that regulates pain and inflammation. The candidate has demonstrated superior pain relief than THC and fewer adverse effects in preclinical studies. The company has started the safety pharmacology package and is moving towards Phase I readiness. A patent application was filed in early 2024.

Programme 4 - intriguing oncology lead

Programme 4 is based on a novel cannabinoid derivative aimed at treating solid tumours. A possible mode of action in our view is that it might selectively block an endocannabinoid receptor. This receptor is also expressed by immune cells and plays a role in modulating inflammation. Overall, the aim seems to be to lower the natural limitations on the immune response to enable therapies like checkpoint inhibitors to work more effectively. Checkpoint inhibitors are infused antibodies whereas OCT's proposed agent is envisaged as an oral product based on data to date. A lead compound is expected to be designated in 2024. This will then need pre-clinical workup and evaluation so could be clinic-ready from 2026; these studies are not predictable as the compound has to meet strict criteria.

Interestingly, OCT has identified a research organisation that can supply matched tumour and white blood (immune) cell samples from individual patients. This is a useful test system since the immune cells (PBMCs; Peripheral Blood mononuclear Cells) from the patient have been programmed to tolerate the tumour cells. If the compounds being developed by OCT can overcome this tolerance, the PBMCs should attack and kill the tumour cells. This is the general basis of immune-oncology with products like Keytruda (pembrolizumab). However, these blockbuster products are monoclonal antibodies and expensive. The OCT programme 4 aims to find a smaller and cheaper orally available product with similar effects. Although we know little about this programme, we would expect it to be developed as an adjuvant product unless it shows dramatic efficacy. It is also worth noting that such anti-cancer drugs can have powerful and dangerous side effects by unleashing a poorly controlled immune response.

Outlook

OCT's ability to progress depends on funding in Q1CY24 from a low market capitalisation. With adequate funding in place, the MAD stage of the 201 development can progress and possibly b401 can enter the clinic. Of these two, 401 could progress faster as both THC and CBD are well understood pharmacologically and the metered dose system is again well understood from other respiratory products. Further, the TN indication could give a fast readout. The 401 programme is "Phase 1-ready", TN is an unserved orphan market and could be a lucrative franchise.

Programmes 3 and 4 are in earlier development. Programme 3 targets the large and not well-served neuralgic pain market. Programme 4 seems more intriguing and speculative but could be a novel approach to a very large and lucrative cancer franchise. We suggest that this would need partnering fairly early if the data looks good.

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London
+44 207 989 0813
The Business Centre
6 Wool House
74 Back Church Lane
London E1 1AF

New York
+1 347 449 0879
767 Third Avenue
Floor 17
New York
NY 10017

Vancouver
+1 604-688-8158
Suite 965
1055 West Georgia Street
Vancouver, B.C. Canada
V6E 3P3

Sydney
+61 (0) 2 9280 0700
Suite 102
55 Mountain Street
Ultimo, NSW 2007