Introduction

There are various applications of Cannabis Products - Medical Cannabis route for patients, Pharma cannabinoid based drugs (such as Epidiolex and Sativex) and CBD based health and wellness products, each requiring a different level of R&D and regulatory approval.

Israel is has a unique potential to lead the Medical Cannabis area thanks to its expertise in advanced agricultural technologies, in research on the effect of cannabis on the human body (a field defined and established by Prof. Raphael Mechoulam of Hebrew University) and in drug delivery.
In addition, the favorable regulatory conditions position us as one of the only countries worldwide where cannabinoids can be tested in humans in clinical trials (in addition to only Australia and Canada).

**Israel Medical Cannabis Market Overview**

Cannabis for medical use was first approved for use in Israel by the Ministry of Health in 1992 and a formal national medical cannabis program was created in 2007. Israel is currently transitioning to a new framework for medical cannabis regulation. Government Resolution No. 1587 - Cannabis for Medicinal Purposes and Research (CMRP) was issued by the Israeli Ministry of Health on June 6, 2016 and aims to increase medical cannabis accessibility and standardization. It was in pilot mode since April 2018 and is in full effect since April 2019. The medical cannabis market in Israel is expected to grow rapidly after the completion of the pilot period for the CMRP. Based on public information, the number of medical cannabis patients was approximately 12,500 in 2013, 30,000 in 2018, and is estimated to increase to 120,000 by 2022.

Some key aspects of the CMRP include:

- Authorizes exports by approved parties.
- No fixed limit on the number of cultivation and manufacturing licenses that may be granted.
- A requirement for all growers to be GAP certified to breed and cultivate cannabis plants.
- Only GMP certified manufacturers are allowed to sell to pharmacies and to export.
- Patients require a prescription from a physician.
- Patients do not require a permit from the Israeli Ministry of Health.
- Additional physicians are allowed to prescribe medical cannabis.
- All pharmacies can become certified to distribute medical cannabis.
- Patients pay per gram at a freely determined market price.

Israel's cannabis industry can be divided into several segments: Propagation; Growing; Processing/ Manufacturing, and; Selling and Marketing. While most companies are active only in one segment of activity, according to public information few have activity ranging across some aspects of activity, and currently BOL Pharma is the only company in Israel which has a fully a vertically integrated model.
The propagation and growing companies are mainly the companies that received cannabis growing and marketing licenses before the government's reform. The leading company in this segment is Tikun Olam, alongside BOL Pharma, Canndoc Pharma, IMC (Israel Medical Cannabis), Seach, Cann Pharmaceutical (Better Cannabis), Teva Adir, Cannabliss and Pharmocann. The number of companies in these segments is fast growing and there is a growing foreign interest in setting up cannabis facilities in Israel. That, as well as the government's reform after which only companies that can withstand GAP will be allowed to operate, is expected to change the current segments' "map of companies".

In the Processing/Manufacturing segment, three companies have so far completed construction of GMP compliant cannabis production facilities in Israel - Panaxia Pharmaceutical, BOL Pharma and Bazelet Pharma, which is still waiting for approval for its facility.

Pharma companies - expedited development route

Several companies are developing specific cannabis ingredients into a drug, but a drug has a long and expensive road to travel before it reaches the market, so most investors stay clear of this. The advantage of cannabis over other drugs is that cannabis ingredients can be put into clinical trials more easily, without going through safety trials. It is particularly easy to reach human trials for cannabis in Israel, which is therefore developing an advantage in this sector.

There is a growing interest by physicians in conducting clinical trials across a wide range of indications in order to gain controlled data and support evidence-based treatment with cannabinoids. Currently, most clinical trials are observational and based on whole plant extract while in order to follow the drug approval route only pharma grade API's in known dosages can be used, and very few companies can provide those. There are currently a few randomized controlled clinical trials running in Israel.

Israel may become a preferred site for foreign companies for conduct of clinical trials due to the favorable regulatory environment and the availability of high level GCP trained sites.
Export of medical cannabis

In January 2019, the Israeli cabinet approved the export of processed and finished medical cannabis products through the adoption of the resolutions of the team examining the feasibility of exporting medical cannabis as part of the CMPR, which include medical cannabis products such as packed flowers, oils, capsules, and medicated drops. We expect actual export shipments to begin between 6 to 12 months post-approval. For a producer to be permitted to export cannabis products, it must be approved by the Israeli Ministry of Health, the Israel Police Department, have GMP and GSP certifications, and the applicable required import approvals of the destination country. The government has not currently put any quotas in place.

To successfully execute the export potential, companies must adhere to all applicable laws and regulatory requirements in the countries to which they intend to export. Each country has different regulations and requirements which are subject to change governing the import of cannabis into the country, and the use of cannabis within the country.

The innovation of the Israeli Life Sciences industry also contributes to a skyrocketing growth in the number of companies developing technologies in other areas of activity related to Cannabis, such as delivery technologies (vaporizers, drinks, etc.), supportive technologies (for agriculture), biologic data companies (such as NRGene) and devices (Syqe). Today, there are more than 100 companies operating in Israel, of them almost 20 companies are publicly traded, in all sub-sectors. We believe that this number will continue to increase and will be one of growth engines of the life science industry in Israel.

Based on public information