TBD Therapeutics

Developing therapeutic treatment for **Neuropathic Pain** with a novel, synthetic **non-opioid** small molecule (CB2 receptor agonist)

TBD Therapeutics Inc.

Is a USA company established
by the Co-Founders :

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Introduction

TBD Therapeutics Inc. is an early-stage start-up planning:

- To address the serious unmet need in treating **Neuropathic Pain** with a safe, efficacious, synthetic, non-narcotic pharmaceutical drug.
- There is an urgent need to find alternative safer treatments to fight the opioid painkillers crisis. Opioids are the deadliest drug type.
- The active ingredient is a proprietary novel synthetic CB2 receptor agonist.

Neuropathic Pain is an unmet need

- A debilitating chronic pain common in many health conditions at any age.
- **The available treatments are associated with serious side effects and a high risk of addiction.**
- Better treatment will improve health, quality of life of patients & their families, leading to much greater Longevity.

The global Neuropathic Pain market

- **Accounted for over US$ 6,313.4 Mn in value in 2019 and is estimated to reach around US$ 25 billion by the end of 2027**.

Our Technology/IP: HU-910

- **A novel proprietary camphor based synthetic small molecule**
- **HU-910** possesses analgesic, anti-inflammatory and immuno-protective proven properties.

- **The molecule activates a sequence of processes,** via initial attachment to the CB2 receptors throughout the body's Endo-Cannabinoid System. Resulting in, secretion of natural intrinsic pain & inflammation modulation compounds in the body that can prevent or reduce development of pain and inflammation.
- **It is a safe, efficacious, non-psychoactive** (not a narcotic) CB2 receptor agonist with high affinity to CB2 receptors, high potency and high level of penetration into injured tissues.

- **HU-910** demonstrated equipotent analgesic effect as morphine and ibuprofen in chemotherapy-induced neuropathic pain model in mice.

  Chemotherapy-induced neuropathic pain is one of the many types of chronic neuropathic pain.

Our Technology/IP:HU-910

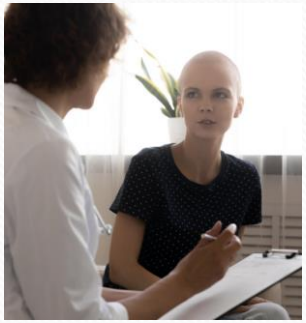
- **We have signed a Licensing Agreement -**The Hebrew University in Jerusalem granting us exclusive rights to develop and commercialize HU-910.

- **Patent – "New Chemical Entity/Composition of Matter"** comprise of a wide range of relevant therapeutic indications, was registered and a patent was granted to Hebrew University, in key strategic markets including the USA, Europe and RoW (rest of world).

- **IP strategy: Protect, Expand & Strength the initial patent, including** :
  - Development of a unique delivery system- per the chosen Route of Administration.
  - Key new findings in specific therapeutic areas, following the initial core Neuropathic Pain indication.

Neuropathic Pain–Main Causes

- Physical Injury & Trauma
- Musculoskeletal health conditions
- Auto-Immune Diseases
- Cancer
- Growing Elderly Population
- Neurological Diseases
- Diabetes
- Central Nervous System Disorders
- Women related conditions
- Alcoholism



Neuropathic Pain – The Solution;
HU-910 solves this significant unmet need

TBD Therapeutics

As an efficacious, safe, non-narcotic drug, HU-910 will:

- Improve patients' compliance with continuous treatment
- Improve patients' daily quality of life
- Improve patients' ability to work and their economical situation
- Improve patient's family members' quality of life
- Reduce side effects in patients who have chronic pain with comorbidities
- Patients are less likely to develop tolerance with chronic use
- Keep patients away from all types of medical facilities, from consuming more and more medications- Reducing drastically healthcare system costs.
- To Conclude- Better treatment will improve health , quality of life and vitality, leading to much greater LONGEVITY.

THE TEAM
Co-Founders & Directors

Esther Farkash

Merav Krasner

<u>The Team at this initial early stage. More team members will be added.</u>

Strategic Selection of a "Power-House" with the knowledge & skill set to fully execute the development plan

- **<u>Pharmaceutical Regulatory Expert</u>**.
- School of Pharmacy graduate with 25+ years experience in Regulatory Affairs of drug development & licensing processes at global leading pharmaceutical companies.
- Vast experience working on Neurology and Psychiatry drugs, including fentanyl and topiramate that are directly relevant for the neuropathic pain indication.

- **<u>Marketing & Commerciallization Strategy Expert</u>**.
- BSc in life Science, with 25+ years of commercial experience working in the global pharmaceutical, diagnostics and medical devices industries.
- Strong product development & marketing experience in the CNS, Oncology and Wound Care space.

THE TEAM

Prof. Doron Steinberg

Scientific Advisor

Prof. Doron Steinberg is The Head of the BIOFILM Research Laboratory and a researcher at The Multidisciplinary Center for Cannabinoids research at The Hebrew University in Jerusalem, Israel.

- Prof. Steinberg worked with the molecule designer Prof. Mechoulam on different research projects concerning Endo-Cannabinoids and Cannabinoids and has many patents of which one has evolved into a commercial product- PerioChip, a prescription medicine.

Mrs. Techiya Toaff

Clinical Regulatory & Strategic Expert

- 20+ years experience in clinical research, regulatory and trials in the pharmaceutical industry.
- Worked at the FDA as regulatory project manager.

Dr.....
Pain Specialist

Physician expert in Pain

To Be Decided

THE TEAM

Service providers & Consultants

TBD Therapeutics

ProPharma Group,
Washington D.C.

Regulatory Strategic Plans

- The leading global single-source independent provider of regulatory services for clients in the pharmaceutical, biotechnology and medical devices industries.
- Specializing in regulatory & compliance consulting throughout the full product lifecycle working with the FDA, EMA, and other national agencies throughout Europe.

Gad Consulting Services,
Raleigh, North Carolina

Non-Clinical drug development

- Leaders in nonclinical formulation, all required animal models & studies

HU-910 Development
Completed Milestones

- **Design & Development:** of the molecule HU-910 by Prof. Mechoulam.
- **Patent Granted:** The Hebrew University, Jerusalem, Israel.
- **TBD Therapeutics Inc.** signed an exclusive licensing agreement with the university.
- **Initial Proof of Concept**: Pre-clinical study at the university laboratories with HU-910 demonstrated equipotent analgesic effect as morphine and ibuprofen in chemotherapy-induced neuropathic pain (as one type of neuropathic pain).
- **Pre-Clinical Regulatory Strategic Plan:**
  Prepared, ready for the start of the pre clinical studies.
- **Pre-Clinical service providers to conduct the required animal studies:**
- Identified and quotes received.
- **Funding** of this project – till now > $150,000 were invested privately by the Co-founders.

HU-910 Development
Planned Milestones

- **IND enabeling Pre-Clinical Studies:**
  Efficacy and Route of Administration studies to obtain evidence-based data for FDA pre-IND discussions towards fast- track designation process. 2025-2026

- **Fundraising:**
  First round of at least $ 1 M.
  Second round additional $ 5 M - 2025-2006.

- **Go To Market/Channel strategy:**

1. Identify strategic partners for full development & commercialization for the therapeutic indication Neuropathic Pain.
2. Exit options
3. Continue development of more therapeutic indications per patent.

Investment Request to Fund Core Activities

In order to reach key milestones we will require:

TBD Therapeutics

- **At least $ 1 M**

To start the required Pre-Clinical Efficacy Studies for different types of Neuropathic Pain and Rute of Administration tests.

- **Next fundraising round**

Additional $ 5 M to continue the safety preclinical studies, and prepare for FDA discussions regarding fast-track designation process.

TBD Therapeutics would like to pursue a SAFE (Simple Agreement For Future Equity) investment agreement offering investors future equity in the company in exchange for their investment. We will consider other types of investments.

Thank You

TBD Therapeutics