Therapix Biosciences Completes Pre-IND Communication With FDA on THX-110 for Tourette Syndrome: Clinical Development to Proceed as Projected

TEL AVIV, Israel, Feb. 7, 2018 /PRNewswire/ -- Therapix Biosciences Ltd. (Nasdaq: TRPX) ("Therapix" or the "Company"), a specialty clinical-stage pharmaceutical company focusing on the development of cannabinoid-based treatments, announced today that it has held a pre-Investigational New Drug (pre-IND) communication with the U.S. Food and Drug Administration (FDA) to discuss the regulatory pathway for the development of THX-110 for the treatment of Tourette Syndrome.

"Following this informative communication with the FDA, we can confirm that the IND for THX-110 will not require any additional nonclinical data to support a phase IIb study in the the United States. We intend to submit the a NDA via the 505(b)(2) pathway. We believe that this enables us to continue our clinical program with minimum risk, which is consistent with our platform of repurposing and reformulating for unmet and under-served needs for Tourette Syndrome. We expect to evaluate THX-110 in a phase IIb clinical study in the second quarter of 2018," said Dr. Adi Zuloff-Shani, Chief Technology Officer at Therapix.

"THX-110 has the potential to become the first cannabinoid based medicine for Tourette Syndrome. Currently, two antipsychotic agents are the only FDA-approved medications for this neurological disorder: Haloperidol and Pimozide. However, these drugs are also often associated with significant adverse events," said Dr. Ascher Shmulewitz, Chairman and interim CEO of Therapix. "If approved, THX-110 could provide people who suffer from Tourette Syndrome with a treatment alternative to the antipsychotic agents," Dr. Shmulewitz added.

About Therapix Biosciences:
Therapix Biosciences Ltd. is a specialty clinical-stage pharmaceutical company led by an experienced team of senior executives and scientists. Our focus is creating and enhancing a portfolio of technologies and assets based on cannabinoid pharmaceuticals. With this focus, the company is currently engaged in the following drug development programs based on repurposing an FDA-approved synthetic cannabinoid (dronabinol): THX-110 for the treatment of Tourette syndrome (TS); THX-130 for the treatment of Mild Cognitive Impairment (MCI) and Traumatic Brain Injury (TBI); THX-120 for the treatment of Obstructive Sleep Apnea (OSA); and THX-150 for the treatment of infectious diseases.
Please visit our website for more information at www.therapixbio.com

About THX-110
THX-110 is a combination drug candidate for the treatment of Tourette syndrome and Obstructive Sleep Apnea. It is based on two components: (1) dronabinol (an FDA approved synthetic analog of Δ9-tetrahydracannabinol, or "THC"), which is the psychoactive molecule in the cannabis plant, and (2) palmitoylethanolamide ("PEA"), which is an endogenous fatty acid amide that belongs to the class of nuclear

factor agonists, which are proteins that regulate the expression of genes. The combination of THC and PEA may induce a reaction known as the "entourage effect". The basic tenet of the entourage effect is that cannabinoids work together, or possess synergy, and affect the body in a mechanism similar to the body's own endocannabinoid system, which is a group of molecules and receptors in the brain that mediates the psychoactive effects of cannabis. This entourage effect may account for the pharmacological actions of PEA. Based on an activity enhancement of other physiological compounds, PEA may indirectly stimulate the cannabinoid receptors by potentiating their affinity for a receptor or by inhibiting their metabolic degradation, and by doing so, may increase the uptake of cannabinoid compounds, such as THC. Thus, it is speculated that the presence of the PEA molecule could increase the efficacy of orally administered THC, while reducing the required dosage and decreasing associated deleterious adverse events.

About Tourette Syndrome
Tourette Syndrome (TS) is a neuropsychiatric disorder, characterized by physical (motor) tics and vocal (phonic) tics. Motor or phonic tics are sudden, brief, intermittent, involuntary or semi-voluntary movements or sounds, respectively. They typically consist of brief, coordinated, repetitive movements, gestures, or utterances that mimic fragments of normal behavior. Tic symptoms of TS typically manifest between 4 and 6 years of age, and peak in severity between the ages of 10 and 12 years. However, they often improve over the course of adolescence. Motor tics generally precede the development of phonic tics in TS, and the onset of simple tics usually predates that of complex tics.

TS appears in a wide range of tics severity, from mild symptoms that do not cause serious impairment and often go unnoticed, to loud noises and forceful movements that can result in self-injury. Many with TS experience additional neurobehavioral problems and co-morbidities including OCD and ADHD.

The most severe cases of the disease are often observed in adults. The persistence of the disease into adulthood may have serious consequences that may include self-injurious tics and those that cause social unease, such as echolalia (repeating other people's words), and coprolalia (uttering swear words). Reports on TS adults who exhibited poor response to medications and were hospitalized due to deterioration of their clinical state further support the deleterious effect of the disease in adult patients.

Forward-Looking Statements:
This press release contains forward-looking statements about the Company's expectations, beliefs, and intentions. Forward-looking statements can be identified by the use of forward-looking words such as "believe", "expect", "intend", "plan", "may", "should", "could", "might", "seek", "target", "will", "project", "forecast", "continue" or "anticipate" or their negatives or variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical matters. Such forward-looking statements used in this press release include, among other things, references to the clinical and commercial potential of product candidates. Actual results could differ from those projected in any forward-looking statements due to numerous factors. Such factors include, among others, our ability to raise the additional funding needed to continue to pursue our business and product development plans, the inherent uncertainties associated with developing new products or technologies, our ability to obtain regulatory approval for our product candidates, our ability to commercialize our product candidates, competition in the industry in which we operate and overall market conditions. Any forward-looking statement in this press release speaks only as of the date of this press release. The Company undertakes no obligation to publicly update or review any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by any applicable securities laws. More detailed information about the risks and uncertainties affecting the Company is contained under the heading "Risk Factors" in Therapix Biosciences Ltd.'s annual report on Form 20-F dated May 1, 2017 filed with the SEC, which is available on the SEC's website, www.sec.gov.

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Additional assets available online:

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