

# Therapix Signs Formulation Development and Clinical Manufacturing Agreement with Catalent for THX-TS01

## First Time Tetrahydrocannabinol (THC) and Palmitoylethanolamide (PEA) To Be Combined in Proprietary Formulation

TEL AVIV, Israel, Oct. 6, 2017 /PRNewswire/ -- Therapix Biosciences Ltd. (Nasdaq: TRPX) ("Therapix" or the "Company"), a specialty, clinical-stage pharmaceutical company focusing on the development of cannabinoid-based treatments, today announced it has entered into an exclusive agreement with Catalent Pharma Solutions, the leading global provider of advanced delivery technologies and development solutions for drugs, biologics and consumer health products, for the formulation, development and clinical manufacturing of THX-TS01, a first-in-class, proprietary investigational drug candidate for the treatment of the symptoms of Tourette Syndrome.

Pursuant to the agreement, Catalent will develop THX-TS01 in softgel form in support of Therapix's clinical development program and in accordance with current good manufacturing practice (cGMP). The formulation, development, analytical and cGMP manufacturing activities will be conducted at Catalent's primary softgel development and manufacturing facility in St. Petersburg, Florida.

Ascher Shmulewitz, M.D., Ph.D., Therapix's Chairman of the Board of Directors, said, "This is the first time that two cannabinoids, Tetrahydrocannabinol and Palmitoylethanolamide, which we believe work synergistically, are being combined in a proprietary single dose that may potentially provide a turnkey solution to addressing the symptoms of Tourette Syndrome. Our objective in developing THX-TS01 is to enable the commercialization of a more effective treatment for the symptoms of this devastating, unmet medical need. We believe that this agreement may bring us one step closer to this goal."

Dr. Shmulewitz continued, "This agreement with Catalent—a world-class drug development, delivery and supply organization—reflects our belief in the promise of THX-TS01 as we look forward to advanced-stage clinical trials and, if successful, commercialization. We could not be more pleased with Catalent as our new development and manufacturing partner."

"The potential benefits of combining Tetrahydrocannabinol and Palmitoylethanolamide into a fully-optimized single dose, are manifold," said Adi Zulloff-Shani, Ph.D., Therapix's Chief Technology Officer. "This unique formulation could offer an enhanced biological effect and extended duration greater than that presented by administration of each component on its own."

### 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 two internal drug development programs based on repurposing an FDA approved synthetic cannabinoid (dronabinol):

THX-TS01 targets the treatment of the symptoms of Tourette Syndrome; and THX-ULD01 targets the high-value and under-served market of mild cognitive impairments and Traumatic Brain Injury (TBI). Please visit our website for more information at [www.therapixbio.com](http://www.therapixbio.com).

### **About Catalent:**

Catalent is the leading global provider of advanced delivery technologies and development solutions for drugs, biologics and consumer health products. With over 80 years serving the industry, Catalent has proven expertise in bringing more customer products to market faster, enhancing product performance and ensuring reliable clinical and commercial product supply. Catalent employs approximately 10,000 people, including over 1,400 scientists, at more than 30 facilities across five continents, and in fiscal 2017 generated more than \$2 billion in annual revenue. Catalent is headquartered in Somerset, New Jersey. For more information, visit [www.catalent.com](http://www.catalent.com).

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### **About THX-TS01**

THX-TS01 is a combination drug candidate for the treatment of the symptoms of Tourette Syndrome and it is based on two components: (1) dronabinol, the active ingredient in an FDA approved synthetic analog of tetrahydrocannabinol ("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 likely increases the efficacy of orally administered THC, while reducing the required dosage and decreasing associated deleterious adverse events.

### **About Tourette Syndrome**

Tourette Syndrome 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. The tics associated with Tourette Syndrome can have significant effects on the academic and social development of children as well as affecting their overall self-esteem and mental health. Although the majority of children experience a decrease in their tics during adolescence, the worst symptoms are usually experienced by adults with intractable Tourette Syndrome.

### **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 THX-TS01 for the treatment of Tourette Syndrome. 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](http://www.sec.gov).

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Additional assets available online: 

<http://therapix.investorroom.com/2017-10-06-Therapix-Signs-Formulation-Development-and-Clinical-Manufacturing-Agreement-with-Catalent-for-THX-TS01>